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In The

Supreme Court of the United States

October Term, 1997

NUTRITIONAL HEALTH ALLIANCE and SOO MAN SHIM, d/b/a NEW NUTRISSERIE,

Petitioners,

vs.

DONNA SHALALA, in her official capacity as Secretary, U.S. Department of Health and Human Services, and DAVID KESSLER, Commissioner, Food and Drug Administration,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Second Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED FOR REVIEW

1. What constitutional rule should be applied for a prior restraint of commercial speech?

2. What constitutional rule should be applied for a ban of commercial speech?

3. When is a regulatory ban on commercial speech ripe for judicial constitutional review?

STATEMENT PURSUANT TO RULE 29.6

Nutritional Health Alliance is a not-for-profit corporation whose shares are not publicly traded. Nutritional Health Alliance has no parent companies or nonwholly owned subsidiaries.

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OPINIONS BELOW

For convenience, the opinions and orders rendered below are set forth in the appendices as follows:

The Opinion and Order of the District Court granting petitioners' motion for summary judgment, in part, because of the lack of a regulatory deadline for agency action, but denying petitioners' motion in all other respects as to the constitutionality of the regulatory scheme of prior restraint and ban of commercial speech, is set forth in Appendix E and has been officially reported at 953 F. Supp. 526 (S.D.N.Y. 1997).

The Memorandum and Order of the District Court approving the regulatory deadline established by the Government in response to the District Court's first order is set forth in Appendix B and has not been officially reported.

The Order of the District Court granting petitioners' motion for summary judgment in part and denying it in all other respects, and granting the Government's motion to dismiss petitioners' Complaint, except as to the claim on which the District Court granted relief, are set forth in Appendix D and have not been officially reported.

The Judgment of the District Court entered upon the latter Order is set forth in Appendix C.

The opinion of the Court of Appeals (1) affirming that part of the District Court judgment that approved a 640-day prior restraint (modified by Congress to a 540-day prior restraint) before judicial review; (2) vacating that part of the District Court judgment that reached the question of the constitutionality of the regulatory ban; and (3) dismissing that part of petitioners' action as unripe, is set forth in Appendix A.

STATEMENT OF JURISDICTION

The judgment of the United States Court of Appeals for the Second Circuit, sought to be reviewed herein, was entered on May 15, 1998.

The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1). The jurisdiction of the District Court was based on 28 U.S.C. § 1331.

CONSTITUTIONAL, STATUTORY AND REGULATORY PROVISIONS INVOLVED

The constitutional provision involved herein is the First Amendment to the Constitution of the United States. The statutory provisions are 21 U.S.C. §§ 321(k), (m) & (n); 343(r) & 343-2 of the Food, Drug and Cosmetic Act. The federal regulations involved are 21 C.F.R. §§ 101.14 & 101.70.

Due to the length of these provisions, they are all set forth in full in Appendix F.

STATEMENT OF THE CASE

This Petition presents to the Court an urgent issue regarding a governmental ban in the form of a prior restraint upon the dissemination to the American public of vital, truthful, non-misleading health information about the nutritional components of foods and dietary supplement products. The origin of this case arises from a First Amendment question that this Court left open in *Central Hudson Gas & Electric Corp. v. Public Service Commission*,[1] *i.e.*, whether, or to what extent, the traditional First Amendment prior restraint doctrine applies to commercial speech.[2]

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1. 447 U.S. 557 (1980).

2. *See id.* at 571, n.13.

Petitioner Nutritional Health Alliance (NHA), is a not-for-profit educational and advocacy association of consumers, health professionals, natural products retailers and natural products manufacturers. Petitioner New Nutrisserie is an individual natural products retailer which also markets a line of private label dietary supplement products. Petitioners' constitutional rights to receive and give truthful information about the relationships between the consumption of nutritional products and their actual and potential effects with regard to disease or health related conditions are seriously infringed by the governmental prior restraints and ban at issue in this case.

At issue is a ruling by the Court of Appeals that allows the Government to impose a regulatory scheme of prior restraint upon the dissemination of truthful, non-misleading health information by dietary supplement manufacturers which thereby prevents consumers from receiving, efficiently and in a timely fashion, the latest information about emerging health claims associated with various dietary supplements. Also, separately at issue is the ruling by the Court of Appeals declining to review the constitutionality of the regulatory standard that underpins the Government's prior restraint scheme — a standard that, by definition, bans all emerging and developing health information from dietary supplement labels and labeling.

The First Amendment issues raised by these rulings are particularly compelling where, as in the instant case, we have restraints imposed on speech that is both commercial and non-commercial — *i.e.*, content-based speech that is truthful and non-misleading information about a commercially sold product.[3]

An example cited by petitioners in this case is the health claim stating the benefits of folic acid, for the prevention of

3. All of the products here at issue are presently being lawfully sold to and used by the public. The issue here is what additional information may be given to the public about a product.

neural tube defects in pregnant women, that is authorized for use in the labels and labeling of folic acid dietary supplement products. 21 C.F.R. § 101.79. The health claim for folic acid was known and advocated by reputable medical authorities and by agencies of the U.S. Government for several years before FDA finally approved its use in product labels and labeling. During those years, thousands of babies were born each year with birth defects that could otherwise have been prevented had this information been readily available on products in retail stores where women of childbearing age shopped for food and vitamins.[4]

A more current example is the health claim relating the consumption of Vitamin E to the prevention of heart attacks. The District Court found that the following statement provided by petitioners is the type of truthful health information that can be presented to the public "in a non-misleading fashion":

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4. In 1992, the Center for Disease Control and Prevention ("CDC") issued a recommendation that women of childbearing age consume specific amounts of folic acid to reduce the risk of having a pregnancy affected by neural tube birth defects such as spina bifida. Public Health Service, U.S. Dep't of Health and Human Services, *Recommendations for the Use of Folic Acid to Reduce the Number of Cases of Spina Bifida and Other Neural Tube Defects*, 41 MMWR No. RR-14 (Sept. 11, 1992). The CDC estimated that this recommendation could reduce the number of cases of neural type defects in the United States by *50 percent*. *Id.* Nonetheless, FDA not only would not permit this information to be included in food labeling, but in January 1993, issued rules specifically banning the claim and rejecting the CDC position. 58 Fed. Reg. 2,606 (1993). In response to public criticism, the agency reversed course nine months later and proposed to authorize folic acid and neural tube defect claims. 58 Fed. Reg. 53,254 (1993). It was not until March 1996 — three and a half years later — that final regulations were issued adopting the CDC position. 61 Fed. Reg. 8,752 (1996). As a result of this delay, literally millions of at-risk children were born to mothers who were denied this important health information.

> A study published in the American Medical Journal reports that Vitamin E supplements may reduce the progression of coronary artery disease. This is not an established fact and is still being studied.[5]

This health "claim" is currently banned from the labels and labeling of dietary supplement products because the FDA says the claim has not been shown to be supported by "significant scientific agreement," *see* 63 Fed. Reg. 34,084, 34,090 (1998), even though the claim is supported by several reputable research studies published in recent years. *See, e.g., Serial Coronary Angiographic Evidence that Antioxidant Vitamin Intake Reduces Progression of Coronary Artery Atheroschelerosis*, JAMA (June 21, 1995). The question involved is who should make the decision — the consumer or the government agency — as to what facts should be available to consumers about developing health information, including the status of the scientific research supporting the claim.

The present controversy is founded in the patchwork regulatory structure that currently governs the use of commercial speech in the promotion and sale of dietary supplement products that has resulted from the amendment of the Federal Food, Drug & Cosmetic Act ("FD&C Act")[6] by the Nutrition Labeling and Education Act of 1990 ("NLEA")[7] and by the Dietary Supplement Health and Education Act of 1994 ("DSHEA").[8]

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5. *See* Appendix E at 33a, n.13.

6. 21 U.S.C. §§ 301 *et seq.*

7. Pub. L. No. 101-535, 104 Stat. 2353 (1990).

8. Pub. L. No. 103-417, 108 Stat. 4325 (1994).

Prior to the NLEA, all statements made in connection with the sale of dietary supplement products were subject to the "truthful and non-misleading" standard enforced by the FDA under Section 403(a) of the FD&C Act[9] and by the Federal Trade Commission ("FTC") under Section 15 of the FTC Act.[10] The NLEA added a new subsection to the FD&C Act, codified at 21 U.S.C. § 343(r), which governs the publication of health information on the labels (21 U.S.C. § 321(k)) and labeling (21 U.S.C. § 321(m)) of both conventional foods and dietary supplements.[11] The statute defines as a "health claim" any health information that describes a relationship between a product and a disease or health-related condition. 21 U.S.C. § 343(r)(1)(B).

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9. 21 U.S.C. § 343(a).

10. 15 U.S.C. § 55.

11. The statutory "label" definition is quite broad and includes any:

> display of written, printed, or graphic matter upon the immediate container of any article * * *.

21 U.S.C. § 321(k). "Labeling" has an even more extensive meaning including:

> all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) *accompanying* such article.

21 U.S.C. § 321(m) (emphasis added). The FDA and the courts have interpreted the word "accompanying" with a very broad meaning. FDA's reach goes far beyond what might be thought of as traditional "labeling," and it includes books, articles, circulars, graphics, and other forms of written material used to promote sales of the product. *See, e.g., Kordel v. United States*, 335 U.S. 345 (1948); *Alberty Food Products v. United States*, 194 F.2d 463 (9th Cir. 1952) and *United States v. 7 Jugs [Formalin]*, 53 F. Supp. 746 (D. Minn. 1944) (word "accompany" intended to have broad coverage). Thus, "labeling" includes all kinds of written material which may be on the product label, in the product box, near the product, or even sent separately from the product. A store window display of a book and a product makes the book labeling. *See* 59 Fed. Reg. at 409 (1994).

The stated purpose of the NLEA was to promote public health through the use of valid and understandable claims for food and dietary supplements and to protect the public from fraudulent and misleading claims.[12] The legislation resulted from a Congressional compromise that attempted "to balance the interests of protecting the public from unsubstantiated health claims on the one hand and maximizing the information available to consumers on the other."[13]

The NLEA authorized FDA to issue regulations specifying the conditions under which health claims may be made in the labels and labeling of dietary supplement products,[14] and FDA promulgated regulations requiring the submission of all health claims to FDA for prior approval upon a showing that each claim to be used in labels or labeling is:

> based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles) that there is *significant scientific agreement*, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.[15]

The NLEA mandates that FDA apply this "significant scientific agreement" standard only when reviewing health

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12. *See* 59 Fed. Reg. 395, 402-403 (1994).

13. Appendix E at 26a.

14. 21 U.S.C. § 343(r)(5)(D).

15. 21 C.F.R. § 101.14(c) (emphasis added).

claims made for conventional foods.[16] Nevertheless, FDA has decided to apply the same standard and procedure to dietary supplements.[17]

In the field of nutrition, there are generally two types of health information issues which are regulated under the FDA's jurisdiction. First, there are so-called "emerging" health claims which deal with all the latest information in the fields of nutrition science as they are announced by the scientific community. The second category encompasses information which has already been the subject of many years of review and which FDA finally agrees has achieved the status of "significant scientific agreement." Under NLEA, as interpreted and applied by the Second Circuit in this case, both types of health claims are in the first instance subject to a statutory prior restraint procedure. FDA, however, has already announced that under NLEA, "emerging" health claims will never be approved by the agency.[18]

Before Petitioners commenced the present proceedings, there was no deadline by which the FDA had to publish a final regulation approving or denying any health claim. The District Court in this case ruled that this aspect of NLEA was unconstitutional.[19] FDA responded to this ruling by promulgating a new regulation under which FDA could take up to 640 days to issue a final rule on any health claim submitted to it before judicial review can be sought.[20] However, under the

16. 21 U.S.C. § 343(r)(3)(B)(i).

17. 59 Fed. Reg. at 405 (1994).

18. *See* 59 Fed. Reg. at 405.

19. Appendix E at 35a.

20. 62 Fed. Reg. 28,230 (1997) (to be codified at 21 C.F.R. § 101.70(j)(4)).

Food and Drug Administration Modernization Act of 1997 ("FDAMA"),[21] Congress has now provided that FDA may have up to 540 days to complete its review of a health claim petition.[22] Nevertheless, this is not a true deadline for agency action. If FDA does not complete its review by the end of 540 days, FDAMA only requires FDA to *advise Congress* of the reasons why it has not done so.[23] Under this scheme, FDA review of the health claim could continue indefinitely without any judicial review. The Court of Appeals declined to rule on the constitutionality of this provision of FDAMA, even though it agreed with the District Court's ruling that the initial lack of a deadline for agency action under NLEA was unconstitutional.[24]

Out of "[c]oncern over excessive regulation of dietary supplements and the suppression of truthful information," *NHA v. Shalala*, appendix E at 29a, Congress enacted the Dietary Supplement Health and Education Act of 1994 ("DSHEA") which allows certain health claims to be made in dietary supplement labels and labeling *without prior approval and without "significant scientific agreement."* Specifically DSHEA permits: (1) statements asserting a benefit related to a classical nutrient deficiency disease; (2) claims about the role of a nutrient or dietary ingredient with respect to the structure or function of the human body ("structure/function claims"); and (3) declarations of general well-being from consumption of a nutrient or other dietary ingredient. *See* 21 U.S.C. § 343(r)(6)(A).

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21. Pub. L. No. 105-115, 111 Stat. 2296 (1997).

22. 21 U.S.C. § 343(r)(4)(A)(i).

23. *Id.*

24. Appendix A at 16a-17a.

Under DSHEA, such claims are permitted, *without prior restraint or proof of "significant scientific agreement,"* if the manufacturer has "substantiation" that the assertion is truthful and non-misleading, if the label expressly states, inter alia, that the FDA has not evaluated the claim, and if the FDA was notified within 30 days of the first marketing of the product that bears the claim. *See* 21 U.S.C. §§ 343(r)(6)(B) and (C). DSHEA also created an exemption for "third-party literature" under which manufacturers, *without prior FDA approval or proof of "significant scientific agreement,"* may, "in connection with the sale of a dietary supplement," provide consumers, under a number of conditions, with publications such as articles, chapters from books, or abstracts from scientific publications. *See* 21 U.S.C. § 343-2.

In addition, under FDAMA, health claims recognized by a "scientific body of the United States government, with official responsibility for health protection or research directly relating to human nutrition," or by the National Academy of Sciences, may now be made in labels and labeling upon giving FDA 120-days pre-marketing notice of intended use of the claim.[25] FDA nevertheless retains the power to ban such a claim despite the endorsement of these other agencies.[26] However, these and

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25. 21 U.S.C. § 343(r)(3)(C). It should be noted that these technical distinctions, which determine where and when a health claim is either lawful or unlawful, give no consideration to the true public interest in having the latest health information freely and fully available, and they do nothing to further the government interest in preventing fraud.

26. 21 U.S.C. § 343(r)(3)(D)(i)(I). *See also* 63 Fed. Reg. 34,084, 34,086 (1998). This regulatory scheme has spawned much confusion in the dietary supplement industry. It is unclear as to just what is an allowable structure/function claim and what is an otherwise banned health claim. Even the Report of the President's Commission On Dietary Supplement Labels acknowledges that there is a very fine line between what is allowed and what is unlawful

(Cont'd)

any other "claims" made *in advertising* are subject to the "truthful and non-misleading" standard enforced by the Federal Trade Commission and are not subject to any prior restraint nor to a requirement of "significant scientific agreement."[27]

The following chart conveniently summarizes the scope of the regulatory restrictions as of the enactment of DSHEA and illustrates the irrational and illogical structure of the present regulatory scheme here in issue:

(Cont'd)
and that it is often difficult to draw that line. Commission Report, November 24, 1997, at 36. More recently, the FDA itself has added to the confusion by publishing proposed rules defining the types of statements that can be made under DSHEA concerning the effects of a dietary supplement on the structure or function of the body. 63 Fed. Reg. 23,624 (1998). The proposed rules contain many contradictory examples of what is approved and what is banned. *E.g.*, FDA says that the claim "promotes relaxation" would not be a disease claim and would be permitted under DSHEA, *see id.* at 23,626, whereas, under 21 C.F.R. § 310.519, the claim "helps you relax" is deemed to be a daytime sedative drug claim that is subject to regulatory action.

27. 59 Fed. Reg. 28,388 (1994). The truthful and non-misleading standard is applied to commercial speech — without any prior restraint — under several federal statutes, including other provisions of the FD&C Act itself. *See, e.g.*, 21 U.S.C. § 343(a) (FD&C Act); 15 U.S.C. § 55 (FTC Act); 39 U.S.C. § 3005 (Postal Reorganization Act).

REGULATORY STATUS OF HEALTH CLAIMS FOR DIETARY SUPPLEMENTS

	All Structure/ Function Claims (whether or not supported by "significant scientific agreement")	"Classical" Nutrient Deficiency Disease Information	Emerging Disease and Health Related Information Not Yet Supported By "Significant Scientific Agreement"	Disease and Health Related Claims Supported By "Significant Scientific Agreement"
Advertising	No prior restraints	No prior restraints	No prior restraints	No prior restraints
Third Party Literature "Labeling"	No prior restraints	No prior restraints	No prior restraints	No prior restraints
"Labels and Labeling"	No prior restraints	No prior restraints	PRIOR APPROVAL REQUIRED AND BANNED	PRIOR APPROVAL REQUIRED

It is in this context that petitioners brought suit seeking a declaratory judgment that the NLEA/FDA regulatory scheme, requiring prior approval of dietary supplement health claims in labels and labeling, is a prior restraint that unconstitutionally infringes their right to give and receive truthful, non-misleading health information of great importance to the public. Jurisdiction of the District Court was based on 28 U.S.C. § 1331. As previously noted, the District Court agreed that the NLEA's failure to provide a deadline for agency action was unconstitutional, but nevertheless held that the FDA regulations otherwise met the four-pronged *Central Hudson* test, for the application of the First Amendment to commercial speech,[28] and were therefore constitutional.[29]

Petitioners repeated their contentions in the Court of Appeals. As to petitioners' contention that the NLEA/FDA prior approval requirement is unconstitutional, the Court of Appeals held that the First Amendment prior restraint doctrine does apply to commercial speech, but that the 540-day prior restraint before judicial review on commercial speech provided by the statute was "limited" and "reasonable." The Court of Appeals also decided that petitioners' facial challenge to the NLEA/FDA ban of truthful, non-misleading health claims not found to be supported by "significant scientific agreement" was not ripe for review because petitioners had not first filed a petition and been denied FDA approval for any specific health claim, when in fact FDA has already ruled in an administrative proceeding that it will not approve any emerging health claims no matter how truthful and non-misleading they may be. *See* 59 Fed. Reg. at 405.

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28. *See Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557, 566 (1980).

29. Appendix A at 16a-17a.

The import of the decision of the Court of Appeals is: (1) to allow the government to subject truthful, non-misleading commercial speech to a prior restraint of up to 540-days (and conceivably even longer) before any judicial review; and (2) to allow the government to continue to completely ban truthful, non-misleading commercial speech for which the government determines there is not yet sufficient scientific evidence and support.

The essence of the constitutional protection extended to so-called "commercial speech" under the guiding decisions of this Court is that the protection against government paternalism inherent in the First Amendment must extend, as well, to the arena of ideas in which the public purchases essential goods and services. Now, however, the government posits that only it can determine what is "authoritative" speech that the consumer will be permitted to read on labels and labeling. *See, e.g.*, 63 Fed. Reg. 34,084 (1998). This approach is the epitome of the government censorship which the First Amendment was designed to prevent.

REASONS FOR GRANTING THE WRIT

I.

CERTIORARI SHOULD BE GRANTED TO DETERMINE WHETHER THE SECOND CIRCUIT PROPERLY HELD THAT A PRIOR RESTRAINT OF COMMERCIAL SPEECH IS SUBJECT ONLY TO A MODIFIED *CENTRAL HUDSON* TEST.

In *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557, 566 (1980), this Court established the now familiar four-pronged test by which to measure the constitutional legitimacy of governmental regulation of

commercial speech. However, in the course of its opinion in that case, this Court left open the question of whether the First Amendment protections that prohibit prior restraints of non-commercial speech also extend to prior restraints of commercial speech.

This Court stated in footnote 13 of its *Central Hudson* opinion:

> We have observed that commercial speech is such a sturdy brand of expression that *traditional prior restraint doctrine* may not apply to it. *Virginia Pharmacy Board v. Virginia Citizens Consumer Council*, 425 U.S. at 771-772, n. 24, 48 L.Ed.2d. 346, 96 S.Ct. 1817. And in other areas of speech regulation, such as obscenity, we have recognized that a pre-screening arrangement can pass constitutional muster if it includes adequate procedural safeguards. *Freedman v. Maryland*, 380 U.S. 51, 13 L.Ed.2d. 649, 85 S.Ct. 734 (1965).

447 U.S. 571, n.13 (emphasis added).

Since that landmark decision, the lower courts have frequently taken note of the urgent need for a clear cut exposition of the Constitutional principles to be applied in the area of prior restraint on commercial speech. *See, e.g., Kleiner v. The First National Bank of Atlanta*, 751 F.2d 1193, 1207 (11th Cir. 1985) ("The scope and breadth of the principle against prior restraint in the realm of commercial speech has yet to be charted.") *Texans Against Censorship v. State Bar of Texas*, 888 F. Supp. 1328, 1366 (E.D. Tex. 1995) ("The boundaries of the prior restraint doctrine in the commercial speech area, however, are unclear."); *Berger v. R.I. Bd. of Governors for Higher Education*, 832 F. Supp. 515, 517 (D.R.I. 1993) ("It is

to be noted that it is unclear whether the doctrine of 'prior restraint' even applies to commercial speech.") Indeed, one circuit (in an early opinion) has gone so far as to hold that the prohibitions against prior restraints "have no force in the context of commercial speech." *Record Revolution No. Six v. City of Parma*, 638 F.2d 916, 936 (6th Cir. 1980), *vacated for reconsideration*, 456 U.S. 968 (1982).[30] *See also Westbrook v. Teton County School District*, 918 F. Supp. 1475, 1484 (D. Wyo. 1996).

In the absence of a definitive ruling by this Court, the Court of Appeals in this case held that the First Amendment prior restraint doctrine "does play a role in evaluating the regulation of commercial speech." Appendix A at 15a. However, the Court of Appeals decided in effect that the "role" of the prior restraint doctrine is a very limited one directed towards determining only whether the

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30. The closest this Court has come to addressing this issue was after the decision of the Second Circuit in *Securities and Exchange Commission v. Lowe*, 725 F.2d 892 (2d Cir. 1984), as to which this Court granted certiorari after the dissenting opinion raised the Constitutional issue by noting:

> I conclude that in the wake of *Bolger*, commercial speech which goes beyond mere advertising, so as to include expression of fact and opinion implicating (as does an investment newsletter or a health newsletter, or even a racetrack tout sheet), "substantial individual and societal interest" [citation omitted], now enjoys full First Amendment protection, at least insofar as prior restraint is concerned.

Id. at 906. This Court's subsequent opinion in *Lowe v. Securities and Exchange Commission*, 472 U.S. 181 (1985) did not reach the Constitutional issue, and reversed on other grounds. Justice White, with then Chief Justice Berger and Justice Rehnquist concurring, however, would have reached the Constitutional issue, and argued for a standard which essentially approximates the full *Central Hudson* test. *See id.* at 228-236. The concurring opinion further indicated that prior restraints on speech are "presumptively invalid and may be sustained only under the most extraordinary circumstances." *Id.* at 234.

governmental restrictions are constrained "within reasonable bounds." Appendix A at 16a. Adopting this standard, the Court of Appeals, in an unprecedented ruling sanctioned a 540-day (and possibly longer) prior restraint before judicial review on the communication of vital health information to the American public. *Id.*

It is axiomatic that the timing of speech is often crucial to its impact and that a prior restraint inevitably interferes with the basic exercise of the underlying Constitutional right which is being restrained. *See Elrod v. Burns*, 427 U.S. 347, 373-74, n.29 (1976); *Bantam Books Inc. v. Sullivan*, 372 U.S. 58, 70-71 (1963).

> Prior restraints fall on speech with a brutality and a finality all their own. Even if they are ultimately lifted they cause irremedial loss — a loss in the immediacy, the impact, of the speech. They differ from the imposition of criminal liability in significant procedural respects as well, which in turn have their substantive consequences. The violator of a prior restraint may be assured of being held in contempt; the violator of a statute punishing speech criminally knows that he will be before a jury, and may be willing to take his chance, counting on a possible acquittal. A prior restraint, therefore stops speech more effectively. A criminal statute chills, prior restraint freezes. Indeed it is the hypothesis of the First Amendment that injury is inflicted on our society when we stifle the immediacy of speech.

Bickel, *The Morality of Consent*, 61 (1975), quoted in *S.E.C. v. Lowe*, *supra*, 725 F.2d at 907 (Brieant, J., dissenting).

The promise of review of a prior restraint at some indefinite, future time has long been held not to satisfy Constitutional

requirements. *Heller v. New York*, 413 U.S. 483, 492 (1973); *Freedman v. Maryland*, 380 U.S. 51, 59 (1965). In terms of the most basic notions of First Amendment jurisprudence, the Second Circuit necessarily has gone far astray by authorizing a 540-day prior restraint before judicial review.

It is almost beyond belief that restraints on the dissemination of obscenity are routinely subjected to a maximum and very limited prior restraint period, *see Freedman v. Maryland*, *supra*, while the dissemination of vital health information can be delayed by a prior restraint of up to 540 days or more with devastating consequences to the public health.[31] Surely the government does not have a greater interest in preventing the public from knowing the latest information in the field of health than it does in preventing the dissemination of obscene materials.

Turning to the specifics of the Second Circuit's ruling, it is to be noted that the Court of Appeals has literally invented a new standard whereby only the fourth prong of the *Central Hudson* test[32] is to be applied to prior restraints of commercial speech, and even then only in a modified form. Thus, the Court of Appeals did not apply (or even discuss) the second or third prongs of that test and entirely misapplied *Central Hudson*'s fourth prong.

In violation of *Central Hudson*'s second prong, the Court of Appeals did not examine whether the Government has any substantial interest in imposing a prior restraint on presumably truthful, non-misleading health claims to determine if such claims are supported by "significant scientific agreement." By definition, the "significant scientific agreement" standard requires

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31. See the earlier discussion concerning the claims for folic acid and Vitamin E, *supra*, note 3, and accompanying text.

32. *See* 447 U.S. at 566.

something more than that a health claim be truthful and non-misleading to gain FDA approval. While this Court has in the past found that there are circumstances where government may have a legitimate interest in placing restrictions on the time, place, and manner in which truthful, non-misleading commercial speech can be disseminated,[33] *this Court has never held that Government has any interest in requiring the content of commercial speech to be anything other than truthful and non-misleading before it can be communicated.*[34] Thus, the failure of the Court of Appeals to apply the second prong of the *Central Hudson* test to the prior restraint in this case is particularly egregious because new emerging health claims can never meet the "significant scientific agreement" standard and are therefore subject to perpetual prior restraint no matter how truthful and non-misleading they may be.[35]

In addition, the Court of Appeals did not follow the guidelines laid down in *Rubin v. Coors Brewing Co.*[36] and *44 Liquormart, Inc. v. Rhode Island*,[37] for applying the third prong of *Central Hudson*, which require the Government to make an

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33. *E.g.*, *Kovacs v. Cooper*, 336 U.S. 77 (1949); *Kingsley Books, Inc. v. Brown*, 354 U.S. 436 (1957); *Ohralik v. Ohio State Bar Association*, 436 U.S. 447 (1978); *Florida Bar v. Went For It, Inc.*, 515 U.S. 618 (1995).

34. Indeed, if First Amendment protections apply anywhere, they must *at least* protect the content of speech that is truthful and non-misleading.

35. In fact, FDA admits that its regulatory scheme may indeed ban claims for Vitamin E "in the interim" that might "ultimately be shown to be scientifically valid, truthful, and not misleading." *See* 63 Fed. Reg. 34,084, 34,091 (1998).

36. 514 U.S. 476 (1995).

37. 517 U.S. 484 (1996).

evidentiary showing that a restraint on commercial speech will "significantly advance" the asserted government interest directly and materially.[38] The Court of Appeals did not hold the Government to its burden under this prong of the test, and it is clear on the record that the Government never even attempted to meet that burden. The Government made no evidentiary showing that the NLEA/FDA pre-screening requirement significantly advances the Government's interest in either promoting dissemination of important health information or in preventing fraud. To the contrary, restraining the use of truthful, non-misleading health claims in dietary supplement labels and labeling, prior to FDA approval under the "significant scientific agreement" standard, actually prevents the dissemination to the public of useful health information and in no way precludes the commission of fraud by those who would otherwise flout the law.[39]

Finally, in violation of the fourth prong of the *Central Hudson* test, the Court of Appeals approved the 540-day prior restraint on commercial speech before judicial review without considering whether that restraint was "not more extensive than is necessary."[40] The Court gave no consideration whatsoever to the fact that other less restrictive alternatives for the regulation of health claims are clearly available to the Government, as evidenced by other provisions of the FD&C Act, relating to

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38. *See Coors*, 514 U.S. at 486-490; *44 Liquormart*, 517 U.S. at 505-6.

39. Other federal laws, including the FTC Act and other provisions of the FD&C Act permit statements containing health information to be made without any prior restraint. False and misleading claims made in such statements are nevertheless subject to criminal and civil prosecution. Persons bent on fraud for whom the threat of such prosecution is not a sufficient deterrent will not be further deterred by NLEA's requirement for prior approval.

40. *Central Hudson, supra*, 447 U.S. at 566.

structure/function claims and claims recognized by other U.S. government agencies, and as evidenced by the FTC regulatory enforcement standard.[41]

Instead of applying the entire *Central Hudson* test to the NLEA/FDA prior restraint, the Court of Appeals transformed the fourth prong of *Central Hudson* into a "reasonableness" test. The Court merely decided that the "significant scientific agreement" standard was "sufficiently definite to constrain FDA within reasonable bounds"[42] and that the 540-day prior restraint was "limited" and "reasonable."[43] However, there is nothing in any of this Court's prior commercial speech decisions that would suggest this to be a proper application of First Amendment principles to a prior restraint of such speech. But, even under a "reasonableness" test, the 540-day prior restraint before judicial review allowed by FDAMA is *clearly unreasonable* (as indicated by several of this Court's other prior restraint decisions involving non-commercial speech).[44]

Thus, the entire body of this Court's precedents in the field of commercial speech could be neutralized by the notion that prior restraints can be utilized to bypass the careful four-pronged analysis mandated by *Central Hudson*. Certiorari is therefore fully warranted to delineate the precise rule to be applied to prior restraints of commercial speech.

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41. *See* 21 U.S.C. §§ 343(r)(6)(A), (B) & (C) and §§ 343-2 & 343(r)(3)(C). *See also* 15 U.S.C. § 55.

42. Appendix A at 16a.

43. *Id.*

44. *See, e.g., New York Times Co. v. United States*, 403 U.S. 713 (1971); *Organization For A Better Austin v. Keefe*, 402 U.S. 415 (1971); *Near v. Minnesota*, 283 U.S. 697 (1931); *Schenck v. United States*, 249 U.S. 47 (1919); *Cf., Freedman v. Maryland*, 380 U.S. 51 (1965).

II.

CERTIORARI SHOULD BE GRANTED TO DETERMINE WHETHER THE SECOND CIRCUIT PROPERLY HELD THAT THE REGULATORY BAN ON COMMERCIAL SPEECH WAS NOT RIPE FOR REVIEW WHERE THE GOVERNMENT HAS ALREADY RULED ON THE QUESTION TO BE REVIEWED.

The Court of Appeals also decided that the petitioners' facial challenge to the NLEA/FDA ban of truthful, non-misleading health claims not found to be supported by "significant scientific agreement" was not ripe for review because petitioners had not first requested FDA's approval for any specific claim that was then denied approval under the "significant scientific agreement" standard.[45] The Court of Appeals reasoned that whether a particular health claim is misleading turns in part on whether consumers would be confused about side effects and, therefore, that such a determination cannot be made without a full agency record.[46]

The Court of Appeals was clearly in error on this point because the FDA had already ruled, after a full administrative proceeding that was preceded by notice and comment that, emerging health information based on preliminary research or studies will never be found by FDA to be supported by "significant scientific agreement" — even when it is conceded that the emerging health information may in fact be truthful and non-misleading. Thus the agency had previously asserted that:

> [A] standard for health claims that is based only on Section 403(a)(1) of the Act (21 U.S.C. 343(a) (1)), *or that allows health claims based on the existence of*

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45. Appendix A at 11a.

46. *Id.*

substantial scientific evidence, even though significant scientific agreement about the validity of the claim does not exist, would be inconsistent with Congress' desire to ensure that health claims that are made on food, including dietary supplements, are *scientifically valid.*

* * *

Several comments suggested that FDA adopt the reasonable substantiation standard used by the Federal Trade Commission * * *. The comments asserted that under this policy, FDA could allow manufacturers to make claims provided that the nature of the scientific finding is accurately represented, [and] the degree of evidence is not misrepresented * * *. The comments argued that this policy would facilitate harmonization with the FTC regulations governing the use of health claims in food advertising, *would allow consumers to have access to truthful, nonmisleading, and reliable labeling information*, and would still allow FDA to take action against those dietary supplements bearing health claims that are not properly substantiated.

Arguments that FDA should adopt for dietary supplements FTC's approach for regulating advertising are not consistent with Congress' expectations for health claims * * *. Specifically, as explained above, one of Congress' main purposes in passing the 1990 amendments was to ensure that health claims made in food labeling are scientifically *valid*. No such assurance of scientific *validity* is provided under the standard that FTC must employ. Under that standard, there must be some evidence

> to support a claim, but it need not rise to the level of establishing the claim's *validity*. Thus, the FTC standard is not adequate for health claims.

59 Fed. Reg. 405 (emphasis added).

Indeed, FDA has recently reaffirmed this to be its policy.

> To be the Basis for a Health or Nutrient Content Claim, a Statement Must Be Based on a Deliberative Review of the Scientific Evidence on the Subject of the Statement, and It Should Not Indicate That the Scientific Evidence is Preliminary or Inconclusive.

63 Fed. Reg. 34,084, 34,086 (1998).

In addition, the reasoning of the Court of Appeals was also faulty because there is no question of side effects here in issue. The dietary supplement products herein are entirely legal and being lawfully sold.[47] The information or speech contained in their labeling is separate and apart from any issue of side effects. If any particular product is actually deemed unsafe, FDA has the power to require cautions or warnings or to ban it altogether.[48] This would be so whether the speech here in issue was included in the labeling or not. Thus, the stated concern of the Court of Appeals with side effects was clearly in error and irrelevant and caused it to avoid the real issue respecting the constitutional validity of banning emerging health information under the "significant scientific agreement" standard.

The Court of Appeals did not need a full record on a specific claim to find that no emerging health claim could ever meet the

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47. *See* 59 Fed. Reg. 395, 396 (1994).

48. *See* 21 U.S.C. §§ 334, 342(f)(1)(C).

"significant scientific agreement" standard or that, *at least, some* emerging health claims could be truthful and non-misleading (as the District Court did find).[49]

Therefore, it would have served no useful purpose to first request FDA's approval of a type of health claim that FDA has already said it will not approve. Given that the FDA regulatory scheme does prohibit *at least some* truthful and non-misleading emerging health claims, it would be a futile and meaningless act to submit a petition to FDA, requesting approval of a claim involving developing health information, and then have to wait 540-days (or more) for it to be denied before being able to seek judicial review.

In addition, the Court of Appeals was further in error by declining to review the constitutionality of the FDAMA provision that permits FDA to take up to 540-days to rule on a health claim petition, with the only consequence for not acting within that time frame being a requirement to provide Congress with the "reasons action on the regulation did not occur within such 540-days."[50] Thus, a question now exists as to whether there is a true statutory deadline by which the FDA is required to rule and judicial review can be sought. This is solely an issue of statutory interpretation that is clearly ripe for decision. *See Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967).

Nevertheless, the Court of Appeals decided that "[a] facial challenge to possible extensions to the 540-day review process is not ripe at this time for all the reasons given" for not reviewing the facial challenge to the ban itself. Appendix A at 17a, n.17. This decision of the Court of Appeals is inexplicable in view of its agreement with the District Court's ruling that the initial

49. Appendix E at 33a.

50. 21 U.S.C. § 343(r)(4)(A)(i).

lack of a deadline for agency action under NLEA was unconstitutional.[51] Delaying a decision on the constitutionality of the possible extensions allowed by FDAMA until after a petition is filed with FDA serves no purpose and is clearly unnecessary.

In declining to review petitioners' facial challenge to the NLEA/FDA ban, the Court of Appeals failed to examine that ban under the principles set forth in *Central Hudson*, *Coors*, and *44 Liquormart*. Failure to do so was thus in conflict with this Court's requirement, as made clear in those cases, that a complete ban of truthful, non-misleading commercial speech must be examined with strict scrutiny.[52]

III.

CERTIORARI SHOULD BE GRANTED TO DETERMINE WHETHER THE REGULATORY BAN ON TRUTHFUL, NON-MISLEADING COMMERCIAL SPEECH IS VIOLATIVE OF THE FIRST AMENDMENT.

The essential vice in the present regulatory scheme is the implementation of the "significant scientific agreement" standard as an effective form of FDA censorship with regard to health claims on labels and labeling of dietary supplements. Under 21 U.S.C. § 343(a)(1), food products are misbranded if their label or labeling is false or misleading in any particular. FDA has explained, however, that under the "significant scientific agreement" standard, even claims which would satisfy the basic statutory provision, *i.e.*, that they not be false or misleading in any particular, are nevertheless banned because they are not sufficiently supported in FDA's opinion. *See* 59 Fed. Reg. at 405.

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51. Appendix A at 16a-17a.

52. *See 44 Liquormart*, 517 U.S. at 508 (Stevens, J.).

The role of the FDA as the final arbiter and censor is highlighted by FDA's own description of the dichotomy and disparity between its stringent rule for conclusive validity on labels and labeling, as compared with the general standard applicable to advertising as regulated under the general jurisdiction of the Federal Trade Commission.

> FDA advises that the provisions of this regulation pertain only to a product's label and labeling. This regulation does nothing to censor the content of books, magazines, or advertising.

59 Fed. Reg. at 409.

When implementing its regulations, FDA brushed aside all alternatives suggested to the agency which would have allowed truthful and non-misleading descriptions of the state of scientific knowledge with regard to health information which had not yet been scrutinized by FDA and determined to be supported by "significant scientific agreement." *See* 59 Fed. Reg. at 416.

FDA's insistence on acting as the "guardian of scientific validity" was thus made absolute. FDA insists on banning all label and labeling statements, no matter how truthful and non-misleading unless FDA itself is convinced that the claim is "valid." Irrespective of the more sensible standards applicable to advertising, FDA insists that, within the area of its jurisdiction, FDA must have the final say on what Americans can be told about health claim information.

This NLEA/FDA regulatory ban of truthful, non-misleading commercial speech fails the four-pronged *Central Hudson* test and therefore violates the First Amendment. As noted by the District Court in this case, there is no question but that material about emerging disease-related research concerning

Vitamin E and heart disease can be presented in a truthful and non-misleading fashion. The regulatory ban of such health information violates the First Amendment for the following reasons:

First, because the Government has not shown that it has a substantial interest in suppressing such speech through the use of such an irrational, crazy-quilt system of regulations. The true governmental interest here appears to be — not to give truthful health information and prevent fraudulent and misleading health claims — but rather a philosophy that prevents truthful and non-misleading information from being given to the consumer absent "significant scientific agreement," as decided by the FDA. Imposition of a health philosophy does not qualify as a "substantial" and legitimate governmental interest under the second prong of *Central Hudson*. It is now well established that the Government does not have broad discretion to suppress truthful, non-misleading information for paternalistic purposes.

Second, because the Government did not show, and could not show how the ban materially and directly advances any governmental interest. Failure to do so is in conflict with the decisions of this Court in *Coors* and *44 Liquormart* which require the Government to show through evidentiary support that the ban significantly advances the state interest. Anything less than a finding based on supporting evidence is speculation and conjecture which is insufficient to meet that burden. *See Coors*, 514 U.S. at 486-490; *44 Liquormart*, 517 U.S. at 505-506.

Finally, because the Government did not, and could not, show that the ban is not more extensive than necessary, given the availability of the regulatory alternatives to the NLEA/FDA process, "it necessarily follows" that the NLEA/FDA complete ban of non-approved health claims from dietary supplement labeling "cannot survive" constitutional review. *See 44 Liquormart*, 517 U.S. at 508.

IV.

CERTIORARI SHOULD BE GRANTED TO RECONSIDER THE CONSTITUTIONAL FIRST AMENDMENT RULE APPLICABLE TO COMMERCIAL SPEECH, NON-COMMERCIAL SPEECH, AND HYBRIDS THEREOF.

While the speech in this case is "commercial," it does consist of health information that is heavily weighted towards conveying a non-commercial message. The decision of the Court of Appeals in this case thus squarely raises the question of whether there should be any difference in the rule applying First Amendment protections to prior restraints and bans of truthful, non-misleading commercial speech and to prior restraints and bans of non-commercial speech. This is especially apparent from the finding by the Court of Appeals that "the speech involved is indisputably 'pure commercial' speech"[53] when in fact the Court of Appeals itself noted that the FDA regulation (and thus the speech regulated under it) "pertains to health and safety"[54] — *i.e.*, speech that is content-based and that clearly does more than reflect "offerors communicating offers to offerees."[55]

In *44 Liquormart*, Justice Stevens' opinion noted that the "mere fact that messages propose commercial transactions does not in and of itself dictate the constitutional analysis that should apply to

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53. Appendix A at 16a.

54. *Id.* The Court of Appeals erred, by twice referring to safety concerns in its decision, because the safety of dietary supplement products is not at issue in this case. The dietary supplement products here in issue are being legally sold. The health information that may appear in their labels and labeling is a separate issue. Whether a Vitamin E supplement product that is otherwise lawfully sold is safe is a question that must be separately addressed by FDA. What *is* at issue in this case is speech — *not* safety.

55. *44 Liquormart*, 517 U.S. at 499 (Stevens, J., *quoting Linmark Associates, Inc. v. Willingboro*, 431 U.S. 85, 96 (1977)).

decisions to suppress them."[56] The "commercial" messages that the NLEA/FDA regulations suppress consist of "newsworthy information"[57] that is otherwise entitled to full constitutional protection.[58] In this context, there is no reason to distinguish what is "commercial" and what is "non-commercial." Accordingly, because of the nature of the speech subject to prior restraint and banning under NLEA, this case presents a unique opportunity for this Court to revisit the *Central Hudson* test to consider the circumstances and the manner in which First Amendment protection should be applied to prior restraints and bans of speech that is used for commercial purposes.

CONCLUSION

It is respectfully submitted that a writ of certiorari issue to review the judgment of the United States Court of Appeals.

Respectfully submitted,

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56. *Id.* at 1507. *See also Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60, 81 (1983) ("[W]e must be wary of unnecessary insistence on rigid classifications, lest speech entitled to 'constitutional protection be inadvertently suppressed.' " [citation omitted] (Stevens, J., concurring).

57. *Coors*, 514 U.S. at 494 (Stevens, J., concurring).

58. *Id.*

APPENDIX

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT DECIDED MAY 15, 1998

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

August Term, 1997

(Argued: April 23, 1998 Decided: May 15, 1998)

Docket No. 97-6246

NUTRITIONAL HEALTH ALLIANCE and SOO MAN SHIM, d/b/a NEW NUTRISSERIE,

Plaintiff-Appellants,

- v. -

DONNA SHALALA, in her official capacity as Secretary, U.S. Department of Health and Human Services, and DAVID KESSLER, Commissioner, Food and Drug Administration,

Defendants-Appellees.

Before:

WALKER, CALABRESI, *Circuit Judges,*
and RESTANI,* *Judge*

Appeal from a judgment of the United States District Court for the Southern District of New York (Richard Owen, *Judge),*

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* The Honorable Jane A. Restani, of the United States Court of International Trade, sitting by designation.

rejecting plaintiffs' claim for declaratory and injunctive relief in a facial First Amendment challenge to a statute and regulations governing health claims on dietary supplement labeling. After granting partial summary judgment to the plaintiffs, the district court denied the remainder of plaintiffs' motion for summary judgment, upheld the constitutionality of a limited prior restraint of commercial speech, and entered judgment for defendants.

Affirmed in part and vacated and dismissed in part.

* * *

CALABRESI, *Circuit Judge:*

The principal question before us is whether plaintiffs-appellants may challenge the statute and regulations governing the labeling of dietary supplements[1] before they have submitted any proposed health claims to the Food and Drug Administration ("FDA") pursuant to the regulations and before the FDA has undertaken any enforcement action against them.

Plaintiffs-appellants Nutritional Health Alliance ("NHA"), a nonprofit association of consumers, health professionals, natural product retailers, and natural product manufacturers, and New Nutrisserie, a natural product retailer that also markets a line of private label dietary supplement products, brought a facial First Amendment challenge to the statute and regulations against defendants-appellees Donna Shalala, Secretary of the U.S. Department of Health and Human Services, and David Kessler, then Commissioner of the FDA. The plaintiffs sought

1. Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353, codified as amended at 21 U.S.C. § § 301, 321, 337, 343, 371; 21 C.F.R. §§ 101.14, 101.70.

declaratory and injunctive relief. The defendants moved to dismiss for lack of standing, pursuant to Fed. R. Civ. P. 12(b)(1), and for failure to state a claim upon which relief could be granted, pursuant to Fed. R. Civ. P. 12(b)(6). Plaintiffs cross-moved for summary judgment.

The United States District Court for the Southern District of New York (Richard Owen, Judge) found that the plaintiffs had standing, denied defendants' motion to dismiss, and, in view of the absence of a deadline for final agency action under the statute and regulations, granted plaintiffs' summary judgment motion in part. In all other respects, the district court upheld the regulatory scheme as constitutional. *See NHA v. Shalala,* 953 F. Supp. 526 (S.D.N.Y. 1997).

In response to the district court's ruling, the government established a regulatory deadline within which the FDA had to approve or disapprove any proposed health claim. And the district court found this timetable acceptable. *See NHA v. Shalala,* No. 95 Civ. 4950 (S.D.N.Y. Aug. 14, 1997) (unpublished Memorandum & Order). The court then denied the balance of the plaintiffs' motion, and entered judgment for defendants. *See NHA v. Shalala,* No. 95 Civ. 4950 (S.D.N.Y. Sept. 18, 1997) (unpublished Order). Plaintiffs appealed from this final judgment to the extent (1) that it denied plaintiffs' motion for summary judgment, and (2) that it incorporated previous court orders upholding the constitutionality of the government's regulatory deadline.

I. BACKGROUND

In 1990, Congress enacted the Nutrition Labeling and Education Act ("NLEA"), which amended the Federal Food,

Drug and Cosmetic Act. *See* Pub. L. No. 101-535, 104 Stat. 2353 (1990), *codified as amended at* 21 U.S.C. §§ 301, 321, 337, 343, 371. The NLEA was passed to "clarify and to strengthen the Food and Drug Administration's legal authority to require nutrition labeling on foods, and to establish the circumstances under which claims may be made about the nutrients in foods." *See* H.R. Rep. No. 101-538, at 7 (1990), *reprinted in* 1990 U.S.C.C.A.N. 3336, 3337.

At issue in this case are the NLEA provisions that permit the FDA to limit the health claims that may be made on dietary supplement labels.[2] In 1993, the FDA promulgated regulations (pursuant to the NLEA) that require persons desiring to make health claims on labeling[3] of dietary supplements to petition the FDA for authorization to make such a claim.[4] The regulations state that the FDA will allow

2. Specifically, the statute provides that a health claim on labeling

> made with respect to a dietary supplement of vitamins, minerals, herbs, or other similar nutritional substances . . . shall be subject to a procedure and standard, respecting the validity of such claim, established by regulation of the Secretary.

21 U.S.C. § 343(r)(5)(D). In response to this mandate, the FDA promulgated 21 C.F.R. §§ 101.14, 101.70.

3. The Federal Food, Drug and Cosmetic Act defines "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).

4. Nothing in either the statute or regulations restricts the sale of dietary supplements. *See* 59 Fed. Reg. 395, 396 (1994). Nor does the FDA control the contents of books, magazines, or non-label advertising. The regulation of general advertising of dietary supplements is, instead, within the purview of the Federal Trade Commission, which evaluates ads under a "truthful and non-misleading" standard. *See* 21 U.S.C. § 343(a).

health claims to be made only when "there is significant scientific agreement . . . that the claim is supported by [the scientific] evidence." 21 C.F.R. § 101.14(c).[5] If the FDA finds that a proposed nutrient-disease relationship is supported by significant scientific agreement among experts, it will promulgate, through notice and comment procedures, a regulation authorizing claims to be made about that relationship. *See id.* § 101.14(d)(1). If by contrast, the FDA determines that such agreement does not exist among experts, the claim will not be permitted on labels.

With respect to nutrient-disease claims, the FDA has adopted the following procedures and timetables: First, a party submits a petition with the proposed health claim and attached supporting evidence. The FDA must notify the applicant within 100 days whether the request will be denied or else "filed" for further review. Within the next 90 days, the FDA is required to deny the petition or else to publish a proposed regulation authorizing the health claim. *See id.* § 101.700(j). And within 270 days of the date of publication of a proposed rule authorizing a health claim, the FDA must publish a final regulation approving or denying the claim. *See id.* § 101.700)(4).[6]

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5. The provision reads, in pertinent part, that the FDA will authorize a claim only when it

> determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

21 C.F.R. § 101.14(c).

6. Before plaintiffs brought their action, there was no deadline (imposed (Cont'd)

Appendix A

In 1994, Congress moved to narrow the reach of the FDA's preauthorization scheme, out of "[c]oncern over excessive regulation of dietary supplements and the suppression of truthful information." NHA v. Shalala, 953 F. Supp. at 528. In the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), Pub. L. No. 103-417, 108 Stat. 4325 (amending the NLEA), it allowed certain health claims for dietary supplements to be made without petitioning the FDA. These included: (1) statements asserting a benefit related to a classical nutrient deficiency disease; (2) claims about the role of a nutrient or dietary ingredient with respect to the structure or function of the human body ("structure/function claims"); and (3) declarations of general well-being from consumption of a nutrient

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(Cont'd)
either by statute or by regulation) by which the FDA had to publish a final regulation approving or denying the health claims. The above deadline was developed pursuant to the district court's order to the FDA. The 270 day period is composed of: (1) 75 days for public comment; (2) 150 days for the FDA to consider the comments received, perform any additional analysis based on the comments, respond to the comments, and draft the final rule; (3) 30 days for the review of the final regulation by the Commissioner of the FDA or the Secretary of Health and Human Services; and (4) 15 days for administrative slippage.

This scheme gives the FDA at least 460 days from the time when a petition is submitted before it must publish a final regulation. An additional provision that allowed the agency to extend this deadline for two additional 90 day periods if it showed sufficient need extended the review period to 640 days. *See* 21 C.F.R. § 101.70(j)(4)(ii). The Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (relevant provisions effective February 19, 1998), has, however, added a new statutory deadline to require that if the FDA issues a proposed regulation approving a health claim, final action must be taken within 540 days of the date that the petition was originally received by the FDA. *See* 21 U.S.C. § 343(r)(4)(A)(i). (If the FDA does not meet this deadline, it must provide Congress with the "reasons action on the regulation did not occur within such 540 days." *Id.*)

or other dietary ingredient. *See* 21 U.S.C. § 343(r)(6)(A). Under the DSHEA, such claims are permitted if the manufacturer has "substantiation" that the assertion is truthful and non-misleading, if the label expressly states, *inter alia,* that the FDA has not evaluated the claim, and if the FDA was notified within 30 days of the first marketing of the product that bears the claim. *See id.* § 343(r)(6)(B), (C).[7] In addition, DSHEA created an exemption for "third-party literature" under which manufacturers, without prior FDA approval, may, "in connection with the sale of a dietary supplement," provide consumers with publications such as articles, chapters from books, or abstracts from scientific publications. *See id.* § 343-2.[8]

Despite DSHEA's amendments, it nonetheless remains true that, generally, "emerging health claims" are barred from labels absent prior approval by the FDA.[9] And use of an unauthorized

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7. Such a statement "may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases." 21 U.S.C. § 343(r)(6).

8. These publications, however, may not be false or misleading, may not promote a particular manufacturer or brand of dietary supplement, and may not have appended to them any stickers or other additions. *See* 21 U.S.C. § 343-2(a).

9. The Food and Drug Administration Modernization Act, Pub. L. No. 105, 115, 111 Stat. 2296, does allow claims to be made on labels if they are supported by "an authoritative statement" of certain entities. Thus if some other "scientific body of the United States government, with official responsibility for health protection or research directly relating to human nutrition," or the National Academy of Sciences publishes an authoritative statement about the relationship between a nutrient and a disease or health-related condition, a claim may be made on labels provided that a 120-day pre-marketing notice is given to the FDA. *See id.* § 303, 21 U.S.C.

(Cont'd)

claim subjects the company and its officer to criminal prosecution for issuing a "misbranded" product. *See id.* §§ 331, 333, 343(a)(1), 343(r)(1)(B).

II. DISCUSSION

Plaintiffs make two principal claims on appeal. First, they argue that the statute and regulations violate the strictures of *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980), and impose an impermissible ban on truthful, non-misleading commercial speech.[10] Second,

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(Cont'd)

§ 343(r)(3)(C)(i),(ii). According to the government, the newly enacted provisions apply only to conventional foods, and not to dietary supplements, but in the past the FDA has applied, by regulation, the same standards and procedures to health claims on dietary supplement labeling as to those on conventional food labeling. *See* 59 Fed. Reg. 395 (Jan. 4, 1994). The FDA, however, has not yet issued any proposed regulations indicating whether the "authoritative statement" exception will be applied to dietary supplement labeling.

10. The four-pronged test for the regulation of commercial speech is:

(1) Whether the speech is misleading or does not "concern lawful activity," in which case no further inquiry is needed and the speech may be restricted;

(2) Whether the government's asserted interest in regulating the speech is substantial;

(3) Whether the restraint directly advances the government's interest; and

(4) Whether the legislation is no more extensive than necessary to serve the government's interest. *See Central Hudson*, 447 U.S. at 566.

they claim that the preauthorization scheme required by the FDA for all health claims (including those eventually approved by the FDA) constitutes an unconstitutional prior restraint on commercial speech.

The government renews its argument — rejected below — that the plaintiffs, since they have not identified to this court or to the FDA a single health claim that they actually wish to make and are prevented from putting on a label by the regulations, lack standing to bring this suit. If the suit were nonetheless deemed justiciable, the government argues that the district court was correct in its finding that the regulatory scheme passes muster under Central Hudson. The government further urges us to reject the plaintiffs' second argument on the ground that the prior restraint doctrine is inapplicable to commercial speech.

A. General Challenge to the NLEA: Justiciability

We must first consider whether plaintiffs' preenforcement facial First Amendment challenges to the NLEA and its regulations are ripe for our review. Ripeness is a constitutional prerequisite to exercise of jurisdiction by federal courts. *See Abbott Labs. v. Gardner*, 387 U.S. 136, 148-49 (1967); *Thomas v. City of New York, No.* 97-7822, 1998 WL 210679, at *2 (2d Cir. Apr. 28, 1998). The court, therefore, can raise the issue *sua sponte*. *See Thomas*, 1998 WL 210679, at *2. In evaluating whether a declaratory judgment action is ripe, we consider (1) the fitness of the issues for judicial review, and (2) the injury or hardship to the parties of withholding judicial consideration. *See Abbott Labs.*, 387 U.S. at 149.

Appendix A

1. Fitness for Judicial Review

To determine fitness for judicial review, we must examine, among other factors, whether "consideration of the underlying legal issues would necessarily be facilitated if they were raised in the context of a specific attempt to [apply and/or] enforce the regulations." *Gardner v. Toilet Goods Assoc.*, 387 U.S. 167, 171 (1967); *see In re Combustion Equip. Assoc., Inc., 838* F.2d 35, 37-38 (2d Cir. 1988); *see also Abbott Labs.*, 387 U.S. at 149 (concluding that "the issues presented are appropriate for judicial resolution at this time," where the facial challenge to the regulation involved the purely legal question of whether the regulation at issue exceeded the scope permitted by the underlying statute).

In the instant case, plaintiffs' complaint did not allege any particular health claims that plaintiffs wished to state. Nor did plaintiffs contend that they had ever sought the FDA's authorization to make any such health claim on dietary supplement labels and that permission had been denied or delayed by the FDA.

In the absence of any specific proposed health claim, it is extremely difficult for the court to conduct a *Central Hudson* analysis. Speech that is found to be non-truthful or misleading is not constitutionally protected under the first prong of the *Central Hudson* test. *See Central Hudson*, 447 U.S. at 566 ("At the outset, we must determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading."). And, as the Tenth Circuit noted in the context of a First Amendment challenge to the same statute and regulations as those in the instant case,

> a critical issue in evaluating the constitutionality of commercial speech is whether the speech at issue is truthful or misleading. Without knowing what claims plaintiffs seek to disseminate, this court cannot assess whether such claims are truthful and not misleading. Therefore, an analysis of this issue would rest on mere speculation.

National Council for Improved Health v. Shalala, 122 F.3d 878, 883 n.7 (10th Cir. 1997) (citation omitted).

We agree with the Tenth Circuit.[11] For, without a specific proposed health claim to review, on evidence of record before the FDA, we cannot determine whether the "significant scientific agreement" requirement actually bars any truthful, non-misleading speech. In particular, we note that the parties have here argued at length over whether hypothetical health claims would, when combined with disclaimers of FDA acceptance, be misleading. That question seems to turn in part on whether the claims would confuse consumers with respect to possible side effects. And this issue is particularly difficult to resolve in the abstract and without a full record. We, therefore, conclude that plaintiffs' claim that the NLEA and FDA regulations ban certain categories of commercial speech in violation of the First Amendment is preferably deemed not to be ready for judicial review.

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11. The Tenth Circuit dismissed the case before it as nonjusticiable because plaintiffs lacked standing. In our view, dismissal was correct, but the justiciability question is best seen as one of ripeness. *See* Erwin Chemerinsky, Federal Jurisdiction § 2.4, at 115 ("Ripeness properly should be understood as involving the question of *when may a party seek preenforcement review of a statute or regulation.*").

2. Hardship to the Parties

Even if resolution of a dispute could be facilitated if a court waited for a specific application of the issues in contention, the question may, nonetheless, perhaps be justiciable under the second ripeness factor if the challenged action creates a direct and immediate hardship for the parties.[12] In the instant case, it is undisputed that if plaintiffs do not comply with the statute and regulations, they are subject to criminal liability. *See* 21 U.S.C. §§ 331, 333, 343(a)(1), 343(r)(1)(B). It is, moreover, also true that traditional ripeness analysis has been relaxed somewhat in cases involving facial challenges based on First Amendment grounds. *See Sanger v. Reno,* 966 F. Supp. 151, 161 (E.D.N.Y. 1997) (collecting cases). We must, therefore, examine what specific harm, if any, will be done to the plaintiffs if judicial review is withheld until such time as they have submitted an actual health claim to the FDA. Plaintiffs have alleged much less hardship than the plaintiffs in *Abbott Laboratories.* In that case, a number of drug companies brought

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12. "The relationship between these two parts of the test — fitness and hardship — has never been precisely defined." Ernst & Young v. Depositors Econ. Protection Corp., 45 F.3d 530, 535 (1st Cir. 1995). *Compare Cedars-Sinai Med. Ctr. v. Watkins,* 11 F.3d 1573, 15 81 (Fed. Cir. 1993) (holding that, in order to be ripe, a dispute must meet both prongs of *Abbott Laboratories), with* Laurence H. Tribe, American Constitutional Law § 3-10, at 80 (2d ed. 1988, ("Cases in which early legal challenges are held to be ripe normally present either or both of two features: significant *present* injuries produced by contemplation of a future event; or legal questions that do not depend for their resolution on an extensive factual background."). For purposes of deciding the instant case, we need not define the contours of the ripeness test. Nonetheless, "[w]e acknowledge the possibility that there may be some sort of sliding scale under which, say, a very powerful exhibition of immediate hardship might compensate for questionable fitness . . . or vice versa." *Ernst & Young, 45* F.3d at 535.

a facial challenge to an FDA regulation requiring the inclusion of generic names for prescription drugs on labels and other printed materials. The Supreme Court observed that "[i]f petitioners wish to comply [with the FDA regulation] they must change all their labels, advertisements, and promotional materials; they must destroy stocks of printed matter; and they must invest heavily in new printing type and new supplies." *Abbott Labs.*, 387 U.S. at 152. Plaintiffs in the instant case, however, have alleged no such hardship if we were not to review their claim on the merits.

In fact, the only real burden that denying immediate judicial review imposes on the plaintiffs before us is that they are subjected to a potential 540-day prior restraint while their claim is evaluated.[13] Such a burden does not suffice to render ripe a dispute that is as manifestly unfit for decision as this one is. It may, however, on its own constitute a valid constitutional claim. In effect, then, the second ripeness factor in the case before us

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13. Plaintiffs have appealed the district court's approval of the regulatory deadline giving the FDA 460 days before it must publish a final regulation. (That deadline is subject to two possible 90-day extensions). Subsequent to plaintiffs' appeal, Congress added a new statutory deadline of 540 days. *See supra* note 6. According to the government, "the Modernization Act did not 'set aside' the time limits for FDA action on health claims, which are prescribed by regulations that remain binding." Gov't Br. at 10 n.*. We, nevertheless, will take the statutory deadline of 540 days as the length of the prior restraint. And because the statutory deadline does not differ significantly from the regulatory deadline ruled on by the district court, we construe plaintiffs' prior restraint claim as challenging this statutory deadline period. *See Florida Gen. Contractors v. Jacksonville*, 508 U.S. 656, 662 n.3 (1993) (holding that a case where a challenged statute was repealed and replaced with another one is not moot where "the new ordinance is sufficiently similar to the repealed ordinance that it is permissible to say that the challenged conduct continues").

becomes the same as plaintiffs' second claim — that the statute and regulations impose an unconstitutional prior restraint.

B. Prior Restraint Challenge

1. Ripeness

We note first that this claim is clearly ripe. It involves a purely legal question that is eminently fit for judicial review. Plaintiffs will necessarily be subjected to the prior restraint as a result of our conclusion that we will not consider their underlying argument until they submit an actual health claim for FDA approval. This follows from the fact that even those claims that will eventually be authorized by the FDA — and that are presumably truthful — are nevertheless subject to the allegedly unconstitutional FDA preclearance procedure. We therefore can consider this second challenge on the merits.[14]

See FW/PBS, Inc. v. City of Dallas, 493 U.S. 215, 223-25 (1990) (permitting facial challenge to prior restraint).

2. Merits

Plaintiffs contend that the NLEA/ FDA requirement for prior approval of all health claims appearing on dietary supplement labels (including those that the FDA eventually approves, and are thus presumably truthful and non-misleading)

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14. There is also no doubt that plaintiffs have standing to raise the prior restraint claim. The delay that they will face as soon as they submit a proposed health claim to the FDA constitutes a concrete injury in fact. For during the 540-day FDA review period the manufacturers and retailers will be prohibited from giving, and the consumers prevented from receiving, information allegedly protected by the First Amendment.

is an unconstitutional prior restraint of commercial speech.[15] The government counters that the prior restraint doctrine does not apply to commercial speech.

The government's contention is, however, overbroad. For our court has stated that the prior restraint doctrine does play a role in evaluating the regulation of commercial speech. As we explained in *New York Magazine v. MTA*, 136 F.3d 123 (2d Cir. 1998):

> Although the Supreme Court has indicated that commercial speech may qualify as one of the exceptions to the bar on prior restraints, *see Central Hudson*, 447 U.S. at 571 n.13, we see no reason why the requirement of procedural safeguards [in prior restraint cases] should be relaxed whether speech is commercial or not. . . .
>
> In fact, the test that the Supreme Court regularly applies to commercial speech supports continuing to require procedural safeguards for prior restraints even where commercial speech is involved. That test

15. Plaintiffs have not alleged in their complaint that they wish to make a health claim that falls within one of the DSHEA exemptions to the FDA prior approval scheme. But there is some disagreement between plaintiffs and the government as to whether one of plaintiffs' hypothetical claims in their brief — "[T]ake Vitamin A if you have a Vitamin A deficiency" — is exempt under the 21 U.S.C. § 343(r)(6) classical nutrient deficiency disease exemption. If plaintiffs wish to make a claim that they think falls within one of the DSHEA exemptions, they are permitted to do so as long as they notify the FDA within 30 days of marketing the product. There is thus no prior restraint imposed on plaintiffs in this context. And such a claim presumably would be ripe for review only after the FDA took some action to bar the claim after it had been made.

> requires us to consider "whether the regulation . . . is not more extensive than is necessary to serve [the asserted governmental] interest."

Id. at 131-32 (citations omitted).

The critical question is, therefore, whether the prior restraint of up to 540 days is acceptable under the fourth prong of *Central Hudson.* In this respect, it is significant that the speech involved is indisputably "pure commercial" speech, and that the regulation pertains to health and safety.[16] Under the circumstances, and given the need to protect consumers before any harm occurs, we conclude that the 540-day prior restraint is sufficiently narrowly tailored. It grants a limited, but reasonable, time within which the FDA can evaluate the evidence in support of labeling claims. And it allows for the development of a record on the matter so that a court can determine whether the regulated speech is, in fact, truthful and non-misleading, as is required by the first prong of the Central Hudson test. Significantly, the statutory scheme does not "place [ ] unbridled discretion in the hands of" the FDA to evaluate proposed claims, which is another evil prohibited by prior restraint doctrine. *FW/PBS, Inc.*, 493 U.S. at 225-26 (internal quotation marks and citation omitted). For the "significant scientific agreement" standard for evaluating claims is sufficiently definite to constrain the FDA within reasonable bounds.

We agree with the district court's earlier decision, in effect holding that the absence of a final deadline constituted a prior

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16. The stated purpose behind the NLEA was to promote public health through the use of valid and understandable claims for food and dietary supplement labels, and to protect the public from misleading and fraudulent health claims. *See* 59 Fed. Reg. 395, 402-03.

restraint of unlimited duration, and that without such a deadline, the preauthorization scheme would not pass constitutional muster. *See NHA v. Shalala,* 953 F. Supp. at 530. But we also find that a restraint of up to 540 days, in the context of evaluating, pursuant to defined standards, whether commercial health claims are truthful and non-misleading, is constitutionally valid.[17]

III. CONCLUSION

We, therefore, hold that plaintiffs' first claim — that the NLEA and FDA regulations impose an unconstitutional ban on certain categories of speech — is not ripe for review. Plaintiffs' second claim — that the regulatory scheme constitutes an unconstitutional prior restraint on speech — is ripe for review, and we hold that the 540-day prior restraint is, in this context, constitutional. Accordingly, we AFFIRM the part of the judgment below that approved the FDA's regulatory deadline, we VACATE the part of the judgment that reached the question of the statute's and regulations' comportment with the First Amendment, and we DISMISS that part of the plaintiffs' action as unripe.

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17. We recognize that, according to the statute, if the FDA does not meet this 540 day deadline, it must provide Congress with the "reasons action on the regulation did not occur within such 540 days." 21 U.S.C. § 343(r)(4)(A)(i); see supra note 6. But, in ruling on plaintiffs' *facial* challenge to the prior restraint imposed by the regulations (and now by the statute), we need not consider particular situations where this additional delay might occur, and we express no opinion on this provision's constitutionality. A facial challenge to possible extensions to the 540 day review process is not ripe at this time for all the reasons given in Section II.A. of this opinion.

APPENDIX B — MEMORANDUM AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK DATED AUGUST 1, 1997

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

95 Civ. 4950 (RO)

National Health Alliance and Soo Man Shim d/b/a/ New Nutrisserie,

Plaintiffs,

-v-

Donna Shalala, in her official capacity as Secretary, U.S. Dept. of Health and Human Services, and David A. Kessler, Commissioner, Food and Drug Administration,

Defendants.

MEMORANDUM AND ORDER

OWEN, District Judge

The response of the Food and Drug Administration to the Court's Opinion and Order of January 31, 1997 as published (perhaps prematurely) in the Federal Register of Thursday, May 22, 1997 is not beyond an appropriate range as envisioned by the Court's said opinion. The 270 days, 75 to invite public comment and roughly six months to allow the agency to assess whatever it receives is not unreasonable. Accordingly, on this record at this time, the time frame in that published response is made the order of this Court and the motion is deemed granted accordingly.

Appendix B

The party or parties may hereafter submit a formal order on notice carrying the foregoing into effect.

Dated: New York, New York
August 1, 1997

s/ [illegible]
United States District Judge

APPENDIX C — JUDGMENT OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK FILED SEPTEMBER 19, 1997

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

95 **CIVIL** 4950 (RO)

NUTRITIONAL HEALTH ALLIANCE and SOO MAN SHIM d/b/a NEW NUTRISSERIE,

Plaintiffs,

-against-

DONNA E. SHALALA, in her official capacity as Secretary, U.S. Dept. Of Health and Human Services, and DAVID A. KESSLER, M.D., in his official capacity as Commissioner, Food and Drug Administration,

Defendants.

JUDGMENT

Plaintiffs having moved for summary judgment and defendants having moved for dismissal pursuant to Fed. R. Cv. P. 12(b)(1) & (6) and said motions having come before the Honorable Richard Owen, United States District Judge, who in an Opinion and Order dated January 31, 1997, denied defendants' motion to dismiss, but granted plaintiffs' motion for summary judgment in part; and now, after further examination, the Court on September 17, 1997, having issued its Order granting plaintiffs' motion for summary judgment in part, to the extent set forth in its Order of September 17th and the Opinion dated January 31,

1997, and denying in all other respects; and granting defendants' motion to dismiss on all claims except the claim on which the Court granted relief as set forth in the Court's Order dated September 17, 1997 and the Court's Opinion and Order dated January 31, 1997, it is,

ORDERED, ADJUDGED AND DECREED: That for the reasons stated in the Court's Order of September 17, 1997, and the Court's Opinion and Order dated January 31, 1997, plaintiffs' motion for summary judgment is granted in part, to the extent set forth in each of the Court's Orders, and denied in all other respects; furthermore, defendants' motion to dismiss the complaint is granted on all claims except the claim on which the Court granted relief as set forth in the Court's Opinion and Order dated January 31, 1997.

DATED: New York, New York
September 19, 1997

JAMES M. PARKISON
Clerk of Court

BY: s/ [illegible]
Deputy Clerk

APPENDIX D — ORDER OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK FILED SEPTEMBER 18, 1997

MARY JO WHITE
United States District Attorney for the
Southern District of New York
By: KAY K. GARDINER (KG-4904)
Assistant United States Attorney
100 Church Street — 19th Floor
New York, New York 10007
Telephone: (212) 385-6234

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

95 Civ. 4950 (RO)

NUTRITIONAL HEALTH ALLIANCE and SOO MAN SHIM d/b/a NEW NUTRISSERIE,

Plaintiffs,

-against-

DONNA E. SHALALA, in her official capacity as Secretary, U.S. Dept. of Health and Human Services, and DAVID A. KESSLER, M.D., in his official capacity as Commissioner, Food and Drug Administration,

Defendants.

Appendix D

ORDER

WHEREAS:

1. In an opinion and order dated January 31, 1997, the Court denied defendant's motion to dismiss the complaint pursuant to Fed. R. Civ. P. 12(b)(1) and (6) and granted plaintiffs' motion for summary judgment in part. In opinion and order, the Court upheld the constitutionality of provisions of the Nutrition Labeling and Education Act and its implementing regulations that govern health claims on the label or labeling of dietary supplements, 21 U.S.C. § 343(r)(5)(D), 21 C.F.R. § 101.70, except to the extent that the regulations did not set a time limit for the promulgation of a final rule for such claims. The Court directed the Secretary of Health and Human Services to establish, and submit to the Court for approval, a reasonable time limit for the promulgation of a final rule for a health claim on dietary supplement labels.

2. In response to the Court's order, the Food and Drug Administration promulgated a final regulation (the "Regulation") set forth at 21 C.F.R. § 101.70(j)(4), and submitted the Regulation to the Court on May 28, 1997.

3. In a memorandum and order dated August 1, 1997, the Court ruled that the time frame established by the Regulation is not unreasonable and is not beyond an appropriate range as envisioned by the Court's previous opinion and order.

NOW, THEREFORE, plaintiffs' motion for summary judgment is granted in part, to the extent set forth above and in the Opinion and Order dated January 31, 1997, and denied in all other respects, defendant's motion to dismiss the complaint is granted on all claims except the claim on which the Court granted

relief as set forth above and in the Opinion and Order dated January 31, 1997, and the Clerk is directed to enter final judgment in accordance with this order.

Dated: New York, New York
September 17, 1997

s/ [illegible]
United States District Judge

APPENDIX E — OPINION AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK DATED JANUARY 31, 1997

NUTRITIONAL HEALTH ALLIANCE
and Soo Man Shim d/b/a New Nutrisserie, Plaintiffs,

v.

Donna SHALALA, in her official capacity as Secretary, U.S. Dept. of Health and Human Services, and David A. Kessler, Commissioner, Food and Drug Administration, Defendants.

No. 95 Civ. 4950 (RO).

United States District Court,
S.D. New York.

Jan. 31, 1997

* * *

OPINION AND ORDER

OWEN, District Judge.

Americans spend approximately $3.5 billion a year on vitamins and other dietary supplements, with more than 120 million people taking them regularly. Under the current federal regulatory scheme, retailers and manufacturers are prohibited from making any "health claim"[1] or "disease claim" on the labels of these

1. A "health claim" is any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication . . . characterizes the relationship of any substance to a disease or health-related condition." 21

(Cont'd)

vitamins unless there is a Food and Drug Administration ("FDA") determination that there is "significant scientific agreement" that the claim is valid. Until the mid-1980's there were virtually no health claims on labels because an even stricter standard was in place. In the mid-1980s, however, disease claims, many of them asserted to be unfounded, confusing, and misleading, began appearing on vitamin labels. During the last ten years, Congress, the FDA, the dietary supplement industry, and consumer groups, in an attempt to balance the interests of protecting the public from unsubstantiated health claims on the one hand and maximizing the information available to consumers on the other, have debated whether and under what circumstances to permit these health claims on the labels of vitamins.[2] In 1990, Congress reached a compromise and passed the Nutritional Labeling and

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(Cont'd)

C.F.R. § 101.14(a)(1) (1995). An example of such claim is "fiber cures cancer." In this opinion the terms "health claim" and disease claim" are used interchangeably.

2. At issue here are only the labels and labeling of dietary supplements. A "label" is "a display of written, printed or graphic matter upon the immediate container," while "labeling" means "all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. §§ 32 1 (k), (m) (1994). In this opinion the terms "label" and "labeling" refer to both the labels and labeling of dietary supplements.

These regulations do not restrict the content of books, magazines or advertising. 59 Fed.Reg. 395, 409 (1994). General advertising of dietary supplements is not under the purview of the FDA but within the jurisdiction of the Federal Trade Commission. Federal Trade Commission Act, 15 U.S.C.A. § 55 (1972 & West Supp.1995).

Education Act of 1990 ("NLEA"),[3] which in part created the current framework for permitting health claims on dietary supplement labels. Plaintiffs here challenge, on First Amendment grounds, this NLEA framework requiring advanced FDA authorization for health claims made on vitamin labels.

Plaintiff Nutritional Health Alliance is a non-profit association of manufacturers, distributors, and consumers of dietary supplements, and plaintiff Soo Man Shim d/b/a New Nutrisserie is a natural product retailer that also markets a line of dietary supplements. Plaintiffs (collectively "NHA") seek declaratory and injunctive relief, contending that the NLEA and FDA implementing regulations unconstitutionally infringe protected speech. Defendants Donna Shalala, Secretary of the United States Department of Health and Human Services, David Kessler, Commissioner of the FDA, and the United States (collectively "the Government") move to dismiss NHA's complaint under Fed.R.Civ.P. 12(b)(1) and (6) for lack of standing and failure to state a claim for which relief can be granted, respectively. Plaintiffs cross-move for summary judgment.[4]

Recently, the District Court for the District of Utah addressed the central issues here in *National Council for Improved Health*

3. Pub. L. No. 101-535, 104 Stat. 2353 (1990); *see also* H.R. Rep. No. 538, 101st Cong. 2d Sess. 7 (1990), *reprinted in* 1990 U.S.C.C.A.N. 3336, 3337 (hereinafter "House Report").

4. An *amici curiae* memorandum supporting the Government's position was submitted by the American Cancer Society, American Heart Association, Center for Science in the Public Interest, Public Citizen, and the Consumer Federation of America. Amici assert that if plaintiffs prevail amici's members would be deprived of "the assurance that only truthful and scientifically valid health claims are made for the foods and dietary supplements they purchase and consume." Amici Mem. at 1.

v. Shalala, 893 F.Supp. 1512 (D.Utah 1995) (hereafter *"NCIH"*),[5] and granted the Government's motion to dismiss, finding the framework constitutional. On one issue alone do I disagree.

Under the regulatory scheme now in place, manufacturers submit proposed claims to the FDA for analysis, within the agency's deadlines under 21 C.F.R. § 101.70 (1994) as follows: within 100 days of receiving a petition for a health claim, the FDA must notify the petitioner that the claim is denied or being filed for extensive review; if a claim is filed for such review, within the next 90 days the FDA must either 1) deny the use of the claim, or 2) if it does not deny the claim, publish proposed regulations regarding the claim.[6] There is, however, thereafter, no

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5. Similar actions have also been brought directly to several appellate courts, but those courts have found that they lack original jurisdiction for the cases. *Wellife Products v. Shalala*. 52 F.3d 357 (D.C.Cir.1995); *Mineral Resources Int'l v. Shalala*, 53 F.3d 305 (10th Cir. 1995).

6. Subsection (j) of the regulation establishes the framework:

> (j) Agency action on the petition.
>
> (2) Within 100 days of the date of receipt of the petition. FDA will notify the petitioner by letter that the petition has either been filed for comprehensive review or denied. . . .
>
> (3) Within 90 days of the filing, FDA will by letter of notification to the petitioner:
>
> (i) Deny the petition, or
>
> (ii) Inform the petitioner that a proposed regulation to provide for the requested use of the health claim will be published in the Federal Register. . . . FDA will publish the proposal to amend the

deadline whatsoever imposed on the FDA to promulgate *final* regulations for proposed health claims.[7] The absence of such a deadline here, I conclude, is in conflict with the First Amendment.

After the promulgation of the dietary supplement final rules in January 1994 — which are at issue in this case — the landscape of dietary supplement regulation changed yet again with the enactment of Dietary Supplement Health and Education Act of 1994 ("DSHEA").[8] Concern over excessive regulation of dietary supplements and the suppression of truthful information drove the passage of the DSHEA, and the mandates and tone of the DSHEA signal a shift toward a more permissive approach to health claims on labels. For example, the DSHEA announces Congressional findings of fact highlighting the importance of dietary supplements: "[Although the Federal Government should take swift action against products that are unsafe or adulterated, the Federal Government should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers;" a new "rational Federal framework must be established to supersede

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> regulations to provide for the requested use of the health claim in the Federal Register within 90 days of the date of filing. The proposal will also announce the availability of the petition for public review.

28 C.F.R. § 101.70(j)(1994).

7. Once a health claim is approved by the FDA, others may use that claim without further FDA involvement.

8. Pub.L. No. 103-417, 108 Stat. 4325 (1994). The DSHEA defined dietary supplements in section 3 (codified at 21 U.S.C. § 321(ff) (1994)).

the current ad hoc, patchwork regulatory policy on dietary supplements. . . ."[9] Moreover, upon signing the DSHEA, President Clinton noted that . . .

> . . . manufacturers, experts in nutrition, and legislators, acting in a conscientious alliance with consumers at the grassroots level, have moved successfully to bring common sense to the treatment of dietary supplements under regulation and law. . . .
>
> [I]n recent years, the regulatory scheme designed to promote the interests of consumers and a healthful supply of good food has been used instead to

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9. Congress also found:

> (2) the importance of nutrition and the benefits of dietary supplements to health promotion and disease prevention have been documented increasingly in scientific studies; . . .
>
> (3)(A) there is a link between the ingestion of certain nutrients or dietary supplements and the prevention of chronic diseases such as cancer, heart disease and osteoporosis. . . .
>
> (5) preventive health measures, including . . . appropriate use of safe nutritional supplements will limit the incidence of chronic diseases, and reduce long-term health care expenditures; . . .
>
> (14) dietary supplements are safe within a broad range of intake, and safety problems with the supplements are relatively rare; and
>
> (15)(A) legislative action that protects the right of access of consumers to safe dietary supplements is necessary in order to promote wellness; . . .

P.L. 103-417 § 2; 21 U.S.C.A. § 321 note (West Supp.1995).

> complicate choices consumers have made to advance their nutritional and dietary goals. With perhaps the best of intentions agencies of government charged with promoting the food supply and the rights of consumers have paradoxically limited the information to make healthful choices in an area that means a great deal to over 100 million people.[10]

The DSHEA explicitly exempts a category of claims from the FDA pre-authorization process, so-called "structure/function" statements (such as "Calcium builds strong bones") which involve the way in which a nutrient affects the function or structure of the body. 21 U.S.C. § 343(r)(6). A structure/function claim is permitted so long as the FDA is notified, the manufacturer has substantiation that the claim is truthful and not misleading, and the product contains a disclaimer.[11] Moreover, the DSHEA lays the groundwork for new standards and procedures to replace the FDA pre-approval framework being challenged in this action. These are presently under consideration.

At the threshold, the Government contends that the Court need not reach the merits of the case because plaintiffs do not have standing. However, I find standing, agreeing with the district court's holding in *NCIH* with respect to this question:

> In this case, the plaintiffs' facial challenge of the health claims regulations implicates the First Amendment.

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10. Statement by President Clinton upon signing S. 784, 1995 U.S.C.C.A.N. 3523-1 (Oct. 25, 1994).

11. The following disclaimer must accompany structure/function claims: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease." 21 U.S.C. § 343(r)(6)(C) (1994).

> Additionally, as was the case in Forsyth, every application of the challenged regulations could impermissibly suppress protected speech. Therefore, in light of the expanded notion of standing under the "overbreadth doctrine," this Court determines that plaintiffs have standing to challenge the health claims regulations.

NCIH, 893 F.Supp. at 1516. I also agree with *NCIH,* that the speech here is commercial. *Id.*

I turn, therefore, to the four-prong test established in *Central Hudson Gas & Electric Corp. v. Public Serv. Comm'n of New York,* 447 U.S. 557, 100 S.Ct. 2343, 65 L.Ed.2d 341 (1980), for determining whether particular regulations of commercial speech survive scrutiny under the First Amendment: [12]

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12. Although three Justices of the Supreme Court have recently stated that "[t]he mere fact that messages propose a commercial transactions does not in and of itself dictate the constitutional analysis that should apply to decisions to suppress them," *44 Liquormart, Inc. v. Rhode Island.* __ U.S. __, __, 116 S.Ct. 1495, 1506-07, 134 L.Ed.2d 711 (1996) (STEVENS, J., for three Justices). I note that this case fits squarely within those situations in which these Justices believe the less strict test applies:

> When a State regulates commercial messages to protect consumers from misleading, deceptive, or aggressive sales practices, or requires the disclosure of beneficial consumer information, the purpose of its regulation is consistent with the reasons for according constitutional protection speech and therefore justifies less than strict review.

Id.; but see id., at __, 116 S.Ct. at 1521 (O'CONNOR, J., for four Justices) ("I would resolve this case more narrowly, however, by applying our established *Central Hudson* test to determine whether this commercial speech regulation survives First Amendment scrutiny.").

(1) Whether the speech is *misleading* (if it is misleading or unlawful, no further inquiry is needed and the speech may be restricted);

(2) Whether the government's asserted interest in regulating the speech is *substantial*;

(3) Whether the restraint *directly advances* the government's interest; and

(4) Whether the legislation is *no more extensive* than necessary to serve the government's interest.

Id. at 566, 100 S.Ct. at 2351.

The first three *Central Hudson* prongs require only brief comment. Under the first prong, if the speech is misleading, it can be prohibited. Although the Government argues that health claims that have not been FDA approved are inherently misleading, not all potential health claims are misleading; at least some can be presented in a non-misleading fashion.[13] Accordingly, like the court in *NCIH*, I hold that plaintiffs clear this first *Central Hudson* hurdle. *NCIH*, 893 F.Supp. at 1516.

The second *Central Hudson* prong, whether there is a substantial governmental interest, is clearly met in this case. *NCIH*, 893 F.Supp. at 1518. The legislative history of these provisions reveals that substantial governmental interests drive the NLEA and implementing regulations: preventing the spread

13. Plaintiffs offer examples of non-misleading information: "A study published in the American Medical Journal reports that Vitamin E supplements may reduce the progression of coronary artery disease. This is not an established fact and is still being studied." Pl.Mem. in Opposition at 37.

of unsubstantiated health claims on labels so that consumers may not be deceived and follow unsound health practices; ensuring the reliability of scientific information disseminated in connection with the sale of dietary supplements; and protecting consumers from being induced to purchase products by misleading information on labels.

The third *Central Hudson* prong addresses whether the NLEA and FDA regulations directly advance the Government's substantial interests, and as noted in *NCIH,* the Supreme Court recently articulated the Government's burden: "The government carries the burden of proving the direct and material advancement of its interests. . . . [The government] seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restrictions will in fact alleviate them to a material degree." *NCIH,* 893 F.Supp. at 1518. Here too, I agree with the *NCIH* holding that the Government has shown that the NLEA and FDA regulations directly and materially advance their substantial interests.

It is the fourth *Central Hudson* prong that requires considerable discussion. A regulation may be no more extensive than necessary to serve the Government's interests. The least restrictive means of regulation is not what is required, but rather a "reasonable fit" between the regulation and the Government's interests at issue: "[W]e have not insisted that there be no conceivable alternative, but only that the regulation not burden substantially more speech than necessary to further the government's legitimate interests." *Board of Trustees of State University of N. Y. v. Fox,* 492 U.S. 469, 478, 109 S.Ct. 3028, 3034, 106 L.Ed.2d 388 (1989) (internal quotation marks and citations omitted).

Appendix E

NHA's attack on the "spectrum of speech encompassed" is unpersuasive. The FDA's comments from the final dietary supplement regulations illustrate that the "spectrum of speech" involved does not offend the First Amendment:

> The means that FDA has chosen to further its substantial interests are reasonable, "in proportion to the interests served," and "narrowly tailored to achieve the desired objectives". . . . The regulations specifically target labeling claims about relationships between substances and disease or health-related conditions. They are not intended to restrict the flow of information to the public, but rather to ensure that the scientific validity of the information provided to consumers in the labeling of a product has been established. Indeed, the regulations leave open a broad range of other communication.

59 Fed.Reg. at 423.

It is, however, the absence of any deadline whatsoever for the final authorization of a proposed health claim which the FDA has already preliminarily determined to be valid, which I conclude, fails to meet *Central Hudson's* fourth prong, and thus violates the First Amendment. NHA states:

> [After the initial proposal, *FDA is under no time restriction* whatsoever-there is no deadline-FDA can simply publish a proposed health claim and then allow it to languish for years. There is no statutory time limit requiring FDA to complete its actual consideration of a proposed health claim and to publish it in the Federal Register in final form.

Pl.Mem. in Opposition at 19. Plaintiffs are correct in their analysis of the applicable time frame. The FDA has a total of 190 days to issue a denial or publish a *proposed* regulation, but there is absolutely no deadline for a final regulation. The FDA considered several alternatives, including that the agency issue a final rule authorizing or prohibiting a health claim within 120 days of publication of the proposal, but rejected these recommendations based on its position that a deadline was neither required nor desirable. The FDA in this area asserts the following:

> The comments maintained that the new (proposed] provision [which mandates a specific deadline for a final rule] would correct an obvious oversight in the existing regulations, i.e., the establishment of a firm deadline for a proposed rule but no firm deadline for a final rule. . . . FDA advises that its failure to specify in § 101.70(j) a deadline for the publication of a final rule regarding the use of a proposed health claim *was not an oversight* Section 403(r)(4)(A)(i) does not require that the agency adhere to any deadline for the publication of a final rule. *While FDA could establish such a timeframe by regulation, it does not believe that the adoption of such a requirement would be prudent.* The comment period following the publication of proposed rules is a critical step in determining whether a proposed regulation is appropriate for adoption. In the instance of health claim regulations, significant information concerning the validity of the substance-disease relationship underlying the proposed health claim may be submitted by interested parties during the comment period. Also, the comment period may bring to light a previously unforeseen potential for the use of a health claim, if

> adopted without modification, to be misleading to consumers or to create serious potential threats to the public health. *The agency has no way to guarantee that it will be able to adequately resolve such problems within the suggested time frame. In such instances, if faced with a specific timeframe, FDA would be forced to either deny an otherwise valid health claim petition, or to approve it without erecting the regulatory framework that it believes necessary to ensure that the public health is safeguarded.* Therefore FDA is not adopting the suggested time limit on the issuance of a final rule. However, the agency advises that it is committed to issuing final rules on health claim petitions as quickly as possible consistent with the issues presented and the agency's available resources.

59 Fed.Reg. at 420 (emphasis added).

I do not question the FDA's assurance that it is committed to issuing final regulations "as quickly as possible," but the First Amendment requires more. Health claim petitions that reach this stage have been preliminarily determined by the agency to be supported by significant scientific agreement. By this point in the process, within 190 days of the petition, the FDA has already gathered, reviewed, and analyzed the pertinent scientific information, and the agency expects that, absent significant problems being raised during the public comment period, the proposed claim will become final.

The First Amendment does not permit the FDA to prohibit this speech (presumptively valid, non-misleading health claims that have been preliminarily determined to be supported by significant scientific agreement) for an indefinite period. I deem

this to be so regardless of the motivation, whether it be a possible valid one such as new — perhaps contrary — input,[14] or an impermissible ground, such as failure of agency attention, or a delay due to agency understaffing. Thus, the lack of a firm deadline for the publication of final rules is not a "reasonable fit,[15] The Supreme Court stated in *Fox* that "almost all of the restrictions disallowed under *Central Hudson's* fourth prong have been substantially excessive, disregarding 'far less restrictive and precise means.' " *Fox*, 492 U.S. at 479, 109 S.Ct. at 3034. Here there is a less restrictive and more precise alternative, namely the establishment of a firm deadline. Despite the FDA's position that the adoption of a deadline would not be "prudent," it is constitutionally required.

The Government argues that if significant time has passed after the publication of a proposed rule without the implementation of a final rule, a petitioner could sue the FDA under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 555(b), 702, 706(l), on the grounds that there has been unreasonable delay. Def.Supplemental.Mem. at 3; *see also Cutler v. Hayes*, 818 F.2d 879, 894-899 (D.C.Cir.1987). This potential remedy under the APA does not however cure the constitutional deficiency in this regulatory scheme, nor is it equitable to impose the costs of initiating litigation upon a petitioner whose claim is presumptively supported by significant scientific agreement (in as much as the FDA has issued a proposed rule), and who has already invested considerable time and resources in the authorization process.[16]

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14. This could be handled by an extension, founded on a showing of cause.

15. The court in *NCIH* found that "reasonable time requirements are imposed," but the court did not address the lack of a final deadline. *NCIH, 893* F.Supp. at 1519-1520.

16. I neither find nor imply that the FDA has unreasonably delayed analysis

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Accordingly, a reasonable deadline must be established. I deem it inappropriate in the first instance, for the Court to impose such a deadline. Given the complexity and extensiveness of the regulatory scheme and the scientific expertise involved, I believe the fixing of an appropriate deadline is more properly left to the Secretary of Health and Human Services and the FDA. *See generally Heckler v. Day*, 467 U.S. 104, 119, 104 S.Ct. 2249, 2257, 81 L.Ed.2d 88 (1984) ("[I]t would be an unwarranted judicial intrusion into this pervasively regulated area for federal courts to issue injunctions imposing deadlines with respect to future disability claims.") Thus, the Secretary is directed to establish and submit to the Court for approval, a reasonable time limit for the promulgation of a final rule for a health claim on dietary supplement labels.[17] The Secretary shall, within 90 days of this order, submit such regulation to me for review of its

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(Cont'd)
petitions. Eight petitions, including food and dietary supplement petitions, have been filed with the FDA since 1993. Three were denied within the first 100 days. One was denied within the next 90 days, and two were the subject of proposed rules, one of which was implemented as a final rule within two months of the proposed rule. Def.Supplemental.Mem. at 4-5. App. A-B; Letter front William B. Schultz. Deputy Commissioner for Policy of the FDA, to Jerome J. Kozak, Senior Vice President of International Dairy Foods Association (July 11, 1996) (regarding denial of health claim petition of the relationship between dietary calcium and hypertension); Proposed Rule On Relationship Between Oat Products and Coronary Heart Disease, 61 Fed.Reg. 296 (1996) (proposed Jan. 4, 1996); Proposed Rule on Relationship Between Sugar Alcohols and Nonpromotion of Dental Carries, 60 Fed. Reg. 37507 (1995) (proposed July 7, 1995); Relationship Between Sugar Alcohols and Nonpromotion of Dental Carries, 61 Fed.Reg. 43433 (1996) (to be codified at 21 C.F.R. § 101.80.

17. A similar approach was taken in *Gonzalez v. Freeman*, 334 F.2d 570, 577-580 (D.C.Cir. 1963) (Burger, J.) and *Blankenship v. Secretary of HEW*, 587 F.2d 329, 336 (6th Cir. 1978).

reasonableness and the entry of such further orders as may be appropriate.

Accordingly, I deny defendants' motion to dismiss the complaint and grant NHA's motion for summary judgment to the extent set forth above.

APPENDIX F — CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

Articles in Addition to, and Amendment of, the Constitution of the United States of America, Proposed by Congress, and Ratified by the Legislatures of the Several States Pursuant to the Fifth Article of the Original Constitution

ARTICLE [I]

Congress shall make no law respecting an establishment or religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances.

FOOD, DRUG AND COSMETIC ACT

21 U.S.C. § 321(k), (m) & (n)

(k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

* * *

(m) The term "labeling" means all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

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(n) If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual.

FOOD, DRUG AND COSMETIC ACT
21 U.S.C. § 343(r)

(r) Nutrition levels and health-related claims

(1) Except as provided in clauses (A) through (C) of subparagraph (5), if it is a food intended for human consumption which is offered for sale and for which a claim is made in the label or labeling of the food which expressly or by implication —

(A) characterizes the level of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food unless the claim is made in accordance with subparagraph (2), or

(B) characterizes the relationship of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food to a disease or a health-related condition unless the claim is made in accordance with subparagraph (3) or (5)(D).

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A statement of the type required by paragraph (q) that appears as part of the nutrition information required or permitted by such paragraph is not a claim which is subject to this paragraph and a claim subject to clause (A) is not subject to clause (B).

(2)(A) Except as provided in subparagraphs (4)(A)(ii) and (4)(A)(iii) and clauses (A) through (C) of subparagraph (5), a claim described in subparagraph (1)(A) —

(i) may be made only if the characterization of the level made in the claim uses terms which are defined in regulations of the Secretary,

(ii) may not state the absence of a nutrient unless —

(I) the nutrient is usually present in the food or in a food which substitutes for the food as defined by the Secretary by regulation, or

(II) the Secretary by regulation permits such a statement on the basis of a finding that such a statement would assist consumers in maintaining healthy dietary practices and the statement discloses that the nutrient is not usually present in the food.

(iii) may not be made with respect to the level of cholesterol in the food if the food contains, as determined by the Secretary by regulation, fat or saturated fat in an amount which increases to persons in the general population the risk of disease or a health related condition which is diet related unless —

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(I) the Secretary finds by regulation that the level of cholesterol is substantially less than the level usually present in the food or in a food which substitutes for the food and which has a significant market share, or the Secretary by regulation permits a statement regarding the absence of cholesterol on the basis of a finding that cholesterol is not usually present in the food and that such a statement would assist consumers in maintaining healthy dietary practices and the regulation requires that the statement disclose that cholesterol is not usually present in the food, and

(II) the label or labeling of the food discloses the level of such fat or saturated fat in immediate proximity to such claim and with appropriate prominence which shall be no less than one-half the size of the claim with respect to the level of cholesterol,

(iv) may not be made with respect to the level of saturated fat in the food if the food contains cholesterol unless the label or labeling of the food discloses the level of cholesterol in the food in immediate proximity to such claim and with appropriate prominence which shall be no less than one-half the size of the claim with respect to the level of saturated fat,

(v) may not state that a food is high in dietary fiber unless the food is low in total fat as defined by the Secretary or the label or labeling discloses the level of total fat in the food in immediate proximity to such statement and with appropriate prominence which shall be no less than one-half the size of the claim with respect to the level of dietary fiber, and

(vi) may not be made if the Secretary by regulation prohibits the claim because the claim is misleading in light of the level of another nutrient in the food.

(B) If a claim described in subparagraph (1)(A) is made with respect to a nutrient in a food, the label or labeling of such food shall contain prominently and in immediate proximity to such claim the following statement: "See ____ for nutrition information." In the statement —

(i) the blank shall identify the panel on which the information described in the statement may be found, and

(ii) if the Secretary determines that the food contain a nutrient at a level which increases to persons in the general population the risk of a disease or health-related condition which is diet related, taking into account the significance of the food in the total daily diet, the statement shall also identify such nutrient.

(C) Subparagraph (2)(A) does not apply to a claim described in subparagraph (1)(A) and contained in the label or labeling of a food if such claim is contained in the brand name of such food and such brand name was in use on such food, before October 25, 1989, unless the brand name contains a term defined by the Secretary under subparagraph (2)(A)(i). Such a claim is subject to paragraph (a).

(D) Subparagraph (2) does not apply to a claim described in subparagraph (2)(A) which uses the term "diet" and is contained in the label or labeling of a soft drink if (i) such claim is contained in the brand name of such soft drink, (ii) such brand name was in use on such soft drink before October 25, 1989, and (iii) the use

of the term "diet" was in conformity with section 105.66 of title 21 of the Code of Federal Regulations. Such a claim is subject to paragraph (a).

(E) Subclauses (1) through (v) of subparagraph (2)(A) do not apply to a statement in the label or labeling of food which describes the percentage of vitamin and minerals in the food in relation to the amount of such vitamin and minerals recommended for daily consumption by the Secretary.

(F) Subclause (i) clause (A) does not apply to a statement in the labeling of a dietary supplement that characterizes the percentage level of a dietary ingredient for which the Secretary has not established a reference daily intake, daily recommended value, or other recommendation for daily consumption.

(3)(A) Except as provided in subparagraph (5), a claim described in subparagraph (1)(B) may only be made —

(i) if the claim meets the requirements of the regulations of the Secretary promulgated under clause (B) and

(ii) if the food for which the claim is made does not contain, as determined by the Secretary by regulation, any nutrient in an amount which increases to persons in the general population the risk of a disease or health-related condition which is diet related, taking into account the significance of the food in the total daily diet, except that the Secretary may by regulation permit such a claim based on a finding that such a claim would assist consumers in maintaining healthy dietary practices and based on a requirement that the label contain a disclosure of the type required by subparagraph (2)(B).

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(B)(i) The Secretary shall promulgate regulations authorizing claim of the type described in subparagraph (1)(B) only if the Secretary determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

(ii) A regulation described in subclause (i) shall describe —

(I) the relationship between a nutrient of the type required in the label or labeling of food by paragraph (q)(1) or (q)(2) and a disease or health-related condition, and

(II) the significance of each such nutrient in affecting such disease or health-related condition.

(iii) A regulation described in subclause (1) shall require such claim to be stated in a manner so that the claim is an accurate representation of the matters set out in subclause (ii) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

(4)(A)(i) Any person may petition the Secretary to issue a regulation under subparagraph (1)(A) or (3)(B) relating to a claim described in subparagraph (1)(A) or (1)(B). Not later than 100 days after the petition is received by the Secretary, the Secretary shall issue a final decision denying the petition or file the petition for further action by the Secretary. If the Secretary denies the

petition, the petition shall not be made available to the public. If the Secretary files the petition, the Secretary shall deny the petition or issue a proposed regulation to take the action requested in the petition not later than 90 days after the date of such decision.

(ii) Any person may petition the Secretary for permission to use in a claim described in subparagraph (1)(A) terms that are consistent with the terms defined by the Secretary under subparagraph (2)(A)(i). Within 90 days of the submission of such a petition, the Secretary shall issue a final decision denying the petition or granting such permission.

(iii) Any person may petition the Secretary for permission to use an implied claim described in subparagraph (1)(A) in a brand name. After publishing notice of an opportunity to comment on the petition in the Federal Register and making the petition available to the public, the Secretary shall grant the petition if the Secretary finds that such claim is not misleading and is consistent with terms defined by the Secretary under subparagraph (2)(A)(i). The Secretary shall grant or deny the petition within 100 days of the date it is submitted to the Secretary and the petition shall be considered granted if the Secretary does not act on it within such 100 days.

(B) A petition under clause (A)(i) respecting a claim described in subparagraph (1)(A) or (1)(B) shall include an explanation of the reasons why the claim meets the requirements of this paragraph and a summary of the scientific data which supports such reasons.

(C) If a petition for a regulation under subparagraph (3)(B) relies on a report from an authoritative scientific body of the United States, the Secretary shall consider such report and shall justify any decision rejecting the conclusions of such report.

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(5)(A) This paragraph does not apply to infant formulas subject to section 350a(h) of this title and medical foods as defined in section 360ee(b) of this title.

(B) Subclauses (iii) through (v) of subparagraph (2)(A) and subparagraph (2)(B) do not apply to food which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments.

(C) A subparagraph (1)(A) claim made with respect to a food which claim is required by a standard of identity issued under section 341 of this title shall not be subject to subparagraph (2)(A)(1) or (2)(B).

(D) A subparagraph (1)(B) claim made with respect to a dietary supplement of vitamins, minerals, herbs, or other similar nutritional substances shall not be subject to subparagraph (3) but shall be subject to a procedure and standard, respecting the validity of such claim, established by regulation of the Secretary.

(6) For purposes of paragraph (r)(1)(B), a statement for a dietary supplement may be made if —

(A) the statement claim a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient,

(B) the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading, and

(C) the statement contains, prominently displayed and in boldface type, the following. "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

A statement under this subparagraph may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. If the manufacturer of a dietary supplement proposes to make a statement described in the first sentence of this subparagraph in the labeling of the dietary supplement, the manufacturer shall notify the Secretary no later than 30 days after the first marketing of the dietary supplement with such statement that such a statement is being made.

* * *

FOOD, DRUG AND COSMETIC ACT
21 U.S.C. § 343-2

§ 343-2. Dietary supplement labeling exemptions

(a) In general

A publication, including an article, a chapter in a book, or an official abstract of a peer reviewed scientific publication that appears in an article and was prepared by the author or the editors of the publication, which is reprinted in its entirety, shall not be defined as labeling when used in connection with the sale of a dietary supplement to consumers when it —

(1) is not false or misleading;

(2) does not promote a particular manufacturer or brand of a dietary supplement;

(3) is displayed or presented, or is displayed or presented with other such items on the same subject matter, so as to present a balanced view of the available scientific information on a dietary supplement;

(4) if displayed in an establishment, is physically separate from the dietary supplements; and

(5) does not have appended to it any information by sticker or any other method.

(b) Application

Subsection (a) of this section shall not apply to or restrict a retailer or wholesaler of dietary supplements in any way whatsoever in the sale of books or other publications as part of the business of such retailer or wholesaler.

(c) Burden of proof

In any proceeding brought under subsection (a) of this section, the burden of proof shall be on the United States to establish that an article or other such matter is false or misleading.

Appendix F

FOOD AND DRUG ADMINISTRATION REGULATIONS 21 C.F.R. § 101.14

§ 101.14 Health claims: general requirements

(a) *Definitions.* For purposes of this section, the following definitions apply:

(1) *Health claim* means any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication, including "third party" references, written statements (e.g., a brand name including a term such as "heart"), symbols (e.g., a heart symbol), or vignettes, characterizes the relationship of any substance to a disease or health-related condition. Implied health claims include those statements, symbols, vignettes, or other forms of complication that suggest, within the context in which they are presented, that a relationship exists between the presence or level of a substance in the food and a disease or health-related condition.

(2) *Substance* means a specific food or component of food, regardless of whether the food is in conventional food form or a dietary supplement that includes vitamins, minerals, herbs, other similar nutritional substances.

(3) *Nutritive value* mean a value in sustaining human existence by such processes as promoting growth, replacing loss of essential nutrients, or providing energy.

(4) Dietary supplement means a food, not in conventional food form, that supplies a component to supplement the diet by increasing the total dietary intake of that component.

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(5) *Disqualifying nutrient levels* means the levels of total fat, saturated fat, cholesterol, or sodium in a food above which the food will be disqualified from making a health claim. These levels are 13.0 grams (g) of fat, 4.0 g of saturated fat, 60 milligrams (mg) of cholesterol, or 480 mg of sodium, per reference amount customarily consumed, per label serving size, and, only for foods with reference amounts customarily consumed of 30 g or less or 2 tablespoons or less, per 50 g. For dehydrated foods that must have water added to them prior to typical consumption, the per 50-g criterion refers to the as prepared form. Any one of the levels, on a per reference amount customarily consumed, a per label serving size or, when applicable, a per 50 g basis, will disqualify a food from making a health claim unless an exception is provided in subpart E of this part, except that:

(i) The levels for a meal product as defined in §101.13(l) are 26.0 g of fat, 8.0 g of saturated fat, 120 mg of cholesterol, or 960 mg of sodium per label serving size, and

(ii) The levels for a main dish product as defined in §101.13(m) are 19.5 g of fat, 6.0 g of saturated fat, 90 mg of cholesterol, or 720 mg of sodium per label serving size.

(6) *Disease or health-related condition* means damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition (claims pertaining to such diseases are thereby not subject to §101.14 or §101.70).

(b) *Eligibility.* For a substance to be eligible for a health claim:

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(1) The substance must be associated with a disease or health-related condition for which the general U.S. population, or an identified U.S. population subgroup (e.g., the elderly) is at risk, or, alternatively, the petition submitted by the proponent of the claim otherwise explains the prevalence of the disease or health-related condition in the U.S. population and the relevance of the claim in the context of the total daily diet and satisfies the other requirements of this section.

(2) If the substance is to be consumed as a component of a conventional food at decreased dietary levels, the substance must be a nutrient listed in 21 U.S.C. 343(q)(1)(C) or (q)(1)(D), or one that the Food and Drug Administration (FDA) has required to be included in the label or labeling under 21 U.S.C. 343(q)(2)(A); or

(3) If the substance is to be consumed at other than decreased dietary levels:

(i) The substance must, regardless of whether the food is in conventional food form or dietary supplement form, contribute taste, aroma, or nutritive value, or any other technical effect listed in § 170.3(o) of this chapter, to the food and must retain that attribute when consumed at levels that are necessary to justify a claim; and

(ii) The substance must be a food or a food ingredient or a component of a food ingredient whose use at the levels necessary to justify a claim has been demonstrated by the proponent of the claim, to FDA's satisfaction, to be safe and lawful under the applicable food safety provisions of the Federal Food, Drug, and Cosmetic Act.

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(c) *Validity requirement.* FDA will promulgate regulations authorizing a health claim only when it determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

(d) *General health claim labeling requirements.* (1) When FDA determines that a health claim meets the validity requirements of paragraph (c) of section, FDA will propose a regulation, in subpart E of this part to authorize the use of that claim. If the claim pertains to a substance not provided for in § 101.9 or § 101.36, FDA will propose amending that regulation to include declaration of the substance.

(2) When FDA has adopted a regulation in subpart E of this part providing for a health claim, firms may make claims based on the regulation in subpart E of this part, provided that:

(i) All label or labeling statement about the substance-disease relationship that is the subject of the claim are based on, and consistent with, the conclusions set forth in the regulations in subpart E of this part;

(ii) The claim is limited to describing the value that ingestion (or reduced ingestion) of the substance, as part of a total dietary pattern, may have on a particular disease or health-related condition;

(iii) The claim is complete, truthful, and not misleading. Where factors other than dietary intake of the substance affect

the relationship between the substance and the disease or health-related condition, such factors may be required to be addressed in the claim by a specific regulation in subpart E of this part;

(iv) All information required to be included in the claim appears in one place without other intervening material, except that the principal display panel of the labeling may bear the reference statement, "See ____ for information about the relationship between ____ and ____," with the blanks filled in with the location of the labeling containing the health claim, the name of the substance, and the disease or health-related condition (e.g., "See attached pamphlet for information about calcium and osteoporosis"), with the entire claim appearing elsewhere on the other labeling, Provided that, where any graphic material (e.g., a heart symbol) constituting an explicit or implied health claim appear on the label or labeling, the reference statement or the complete claim shall appear in immediate proximity to such graphic material;

(v) The claim enables the public to comprehend the information provided and to understand the relative significance of such information in the context of a total daily diet; and

(vi) If the claim is about the effects of consuming the substance at decreased dietary levels, the level of the substance in the food is sufficiently low to justify the claim. To meet this requirement, if a definition for use of the term low has been established for that substance under this part, the substance must be present at a level that meets the requirements for use of that term, unless a specific alternative level has been established for the substance in subpart E of this part. If no definition for "low" has been established, the level of the substance must meet the level established in the regulation authorizing the claim; or

(vii) If the claim is about the effects of consuming the substance at other than decreased dietary levels, the level of the substance is sufficiently high and in an appropriate form to justify the claim. To meet this requirement, if a definition for use of the term high for that substance has been established under this part, the substance must be present at a level that meets the requirements for use of that term, unless a specific alternative level has been established for the substance in subpart E of this part. If no definition for "high" has been established (e.g., where the claim pertains to a food either as a whole food or as an ingredient in another food), the claim must specify the daily dietary intake necessary to achieve the claimed effect, as established in the regulation authorizing the claim, *Provided* That:

(A) Where the food that bears the claim meets the requirements of paragraphs (d)(2)(vi) or (d)(2)(vii) of this section based on its reference amount customarily consumed, and the labeled serving size differs from that amount, the claim shall be followed by a statement explaining that the claim is based on the reference amount rather than the labeled serving size (e.g., risk is low in sodium may reduce the risk of high blood pressure, a disease associated with many factors. A serving of __ ounces of this product conforms to such a diet.").

(B) Where the food that bears the claim is sold in a restaurant or in other establishments in which food that is ready for immediate human consumption is sold, the food can meet the requirements of paragraphs (d)(2)(vi) or (d)(2)(vii) of this section if the firm that sells the food has a reasonable basis on which to believe that the food that bears the claim meets the requirements of paragraphs (d)(2)(vi) or (d)(2)(vii) of this section and provides that basis upon request.

(3) Nutrition labeling shall be provided in the label or labeling of any food for which a health claim is made in accordance with § 101.9; for restaurant foods, in accordance with § 101.10; or for dietary supplements of vitamins or minerals, in accordance with § 101.36. The requirements of this paragraph are effective as of May 8, 1993, except:

(i) For menus, for which the requirements of paragraph (d)(3) of this section will be effective May 2, 1997.

(ii) [Reserved]

(iii) For dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances for which the requirements of paragraph (d)(3) of this section will be effective July 5, 1994.

(e) *Prohibited health claim.* No expressed or implied health claim may be made on the label or in labeling for a food, regardless of whether the food is in conventional food form or dietary supplement form, unless:

(1) The claim is specifically provided for in subpart E of this part; and

(2) The claim conforms to all general provisions of this section as well as to all specific provisions in the appropriate section of subpart E of this part;

(3) None of the disqualifying levels identified in paragraph (a)(5) of this section is exceeded in the food, unless specific alternative levels have been established for the substance in subpart E of this part; or unless FDA has permitted a claim despite the fact that a disqualifying level of a nutrient is present in the food

based on a finding that such a claim will assist consumers in maintaining healthy dietary practices, and, in accordance with the regulation in subpart E of this part that makes such a finding, the label bears a referral statement that complies with § 101.13(h), highlighting the nutrient that exceeds the disqualifying level;

(4) Except as provided in paragraph (e)(3) of this section, no substance is present at an inappropriate level as determined in the specific provision authorizing the claim in subpart E of this part;

(5) The label does not represent or support that the food is for infants and toddlers less than 2 years of age except if the claim is specifically provided for in subpart E of this part; and

(6) Except for dietary supplements or where provided for in other regulations in part 101, subpart E, the food contains 10 percent or more of the Reference Daily Intake or the Daily Reference Value for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount customarily consumed prior to any nutrient addition.

(f) The requirements of this section do not apply to:

(1) Infant formulas subject to section 412(h) of the Federal Food, Cosmetic Act, and

(2) Medical foods defined by section 5(b) of the Orphan Drug Act.

(g) *Applicability*. The requirements of this section apply to foods intended for human consumption that are offered for sale,

regardless of whether the foods are in conventional food form or dietary supplement form.

21 C.F.R. § 101.70

§ 101.70 Petitions for health claims.

(a) Any interested person may petition the Food and Drug Administration (FDA) to issue a regulation regarding a health claim. An original and one copy of the petition shall be submitted, or the petitioner may submit an original and a computer readable disk containing the petition. Contents of the disk should be in a standard format, such as ASCII format. (Petitioners interested in submitting a disk should contact the Center for Food Safety and Applied Nutrition for details.) If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The petition shall state the petitioner's post office address to which any correspondence required by section 403 of the Federal, Food, Drug, and Cosmetic Act may be sent.

(b) Pertinent information may incorporated in, and will be considered as part of, a petition on the basis of specific reference to such information submitted to and retained in the files of FDA. Such information may include any findings, along with the basis of the findings, of an outside panel with expertise in the subject area. Any reference to published information shall be accompanied by reprints, or easily readable copies of such information.

(c) If nonclinical laboratory studies are included in a petition, the petition shall include, with respect to each nonclinical study contained in the petition, either a statement that the study has been conducted in compliance with the good laboratory practice

regulations as set forth in part 58 of this chapter, or, if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(d) If clinical or other human investigations are included in a petition, the petition shall include a statement that they were either conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter, or were not subject to such requirements in accordance with §56.104 or §56.105, and a statement that they were conducted in compliance with the requirements for informed consent set forth in part 50 of this chapter.

(e) All data and information in a health claim petition are available for public disclosure after the notice of filing of petition is issued to the petitioner, except that clinical investigation reports, adverse reaction reports, product experience reports, consumer complaints, and other similar data and information shall only be available after deletion of:

(1) Names and any information that would identify the person using the product.

(2) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.

(f) Petitions for a health claim shall include the following data and be submitted in the following form:

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_____
(Date)
Name of petitioner _____

Post office address _____
Subject of the petition _____
Food and Drug Administration,
Office of Food Labeling (HFS-150).
200 C St. SW.
Washington, DC 20204.

The undersigned, _____ submits this petition pursuant to section 403(r)(5)(D) of the Federal Food, Drug, Cosmetic Act with respect to (statement the substance and its health claim).

Attached hereto, and constituting a part, this petition, are the following:

A. Preliminary requirements. A complete explanation of how the substance conforms to the requirements of 1101.14(b) (21 CFR 101.14(b)). For petitions where the subject substance is a food ingredient or a comment of a food ingredient, the petition should compile a comprehensive list of the specific ingredients that will be added to the food to supply the substance in the food bearing the health claim. For each such ingredient listed, the petitioner should state how the ingredient complies with the requirements of §101.14(b)(3)(ii), e.g., that its use is generally recognized as safe (GRAS) listed as a food additive, or authorized by a prior sanction issued by the agency, and what the basis is for the GRAS claim, the food additive status, or prior sanctioned status.

B. Summary of scientific data. The summary of scientific data provides the basis upon which authorizing a health claim

can be justified as providing the health benefit. The summary must establish that based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), there is significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

The summary shall state what public health benefit will derive from use of the claim as proposed. If the claim is intended for a specific group within the population, the summary shall specifically address nutritional needs of such group and shall include scientific data showing how the claim is likely to assist in meeting such needs.

The summary shall concentrate on the findings of appropriate review articles, National Institutes of Health consensus development conferences, and other appropriate resource materials. Issues addressed in the summary shall include answers to such questions as:

1. Is there an optimum level of the particular substance to be consumed beyond which no benefit would be expected?

2. Is there any level at which an adverse effect from the substance or from foods containing the substance occurs for any segment of the population?

3. Are there certain populations that must receive special consideration?

4. What other nutritional or health factors (both positive and negative) are important to consider when consuming the substance?

In addition, the summary of scientific data shall include a detailed analysis of the potential effect of the use of the proposed claim on food consumption, specifically any change due to significant alterations in eating habits and corresponding changes in nutrient intake resulting from such changes in food consumption. The latter item shall specifically address the effect on the intake of nutrients that have beneficial and negative consequences in the total diet.

If the claim is intended for a significant subpopulation within the general U.S. population, the analysis shall specifically address the dietary practices of such group, and shall include data sufficient to demonstrate that the dietary analysis is representative of such group (e.g., adolescents or the elderly).

If appropriate, the petition shall explain the prevalence of the disease or health-related condition in the U.S. population and the relevance of the claim in the context of the total daily diet.

Also, the summary shall demonstrate that the substance that is the subject of the proposed claim conforms to the definition of the term "substance" in §101-14(a)(2).

C. Analytical data that show the amount of the substance that is present in representative foods that would be candidates to bear claim should be obtained from representative samples using methods from the Association of Official Analytical Chemists (AOAC), where is available. If no AOAC method is available, the petitioner shall submit the method used and data

establishing the validity of the method for assaying the substance in food. The validation data should include statistical analysis of the analytical and product variability.

D. Model health claim. One or more model claim that represent label states that may be used on a food label or labeling for a food to characterize the relationship between the substance in a food to disease or health-related condition that is justified by the summary of scientific data provided in section C of the petition. The model health claim shall include:

1. A brief capsulized statement of the relevant conclusions of the summary, and

2. A statement of how this substance helps the consumer to attain a total dietary pattern or goal associated with the health benefit that is provided.

E. The petition shall include the following attachments:

1. Copies of any computer literature searches done by the petitioner (e.g., Medline).

2. Copies of articles cited in the literature searches and other information as follows:

a. All information relied upon for the support of the health claim, including copies of publications or other information cited in review articles and used to perform meta-analyses.

b. All information concerning adverse consequences to any segment of the population (e.g., sensitivity to the substance).

c. All information pertaining to the U.S. population.

F. The petitioner is required to submit either a claim for categorical exclusion under § 25.24 of this chapter or an environmental assessment under § 25.31 of this chapter.

Yours very truly.
Petitioner _____
By _____
(Indicate authority)

(g) The data specified under the several lettered headings should be submitted on separate pages or sets of pages, suitably identified. If such data have already been submitted with an earlier application from the petitioner or any other final petition, the present petition may incorporate it by specific reference to the earlier petition.

(h) The petition shall include a statement signed by the person responsible for the petition that, to the best of his/ her knowledge, it is a representative and balanced submission that includes unfavorable information as well as favorable information, known to him/her to be pertinent to the evaluation of the proposed health claim.

(i) The petition shall be signed by the petitioner or by his/ her attorney or agent, or (if a corporation) by an authorized official.

(j) *Agency action on the petition.* (1) Within 15 days of receipt of the petition, the petitioner will be notified by letter of the date on which the petition was received. Such notice will inform the petitioner that the petition is undergoing agency review

and that the petitioner will subsequently be notified of the agency's decision to file for comprehensive review or deny the petition.

(2) Within 100 days of the date of receipt of the petition. FDA will notify the petitioner by letter that the petition has either been filed for comprehensive review or denied. The agency will deny a petition without reviewing the information contained in B. *Summary of Scientific Data* if the information in A. *Preliminary Requirements* is inadequate in explaining how the substance conforms to the requirements of §101.14(b). If the petition is denied the notification will state the reasons therefor, including justification of the rejection of any report from an authoritative scientific body of the U.S. Government. If filed, the date of the notification letter becomes the date of filing for the purposes of this regulation. A petition that has been denied without filing will not be made available to the public. A filed petition will be available to the public to the extent provided under paragraph (e) of this section.

(3) Within 90 days of the date of filing, FDA will by notification to the petitioner:

(i) Deny the petition, or

(ii) Inform the petitioner that a proposed regulation to provide for the requested use of the health claim will be published in the FEDERAL REGISTER. If the petition is denied, the notification will state the reasons therefor, including justification for the rejection of any report from an authoritative scientific body of the U.S. Government. FDA will publish the proposal to amend the regulations to provide for the requested use of the health claim in the FEDERAL REGISTER within 90 days of the date of the filing. The proposal will also announce the availability of the petition for public review.